A retrospective review of the most common safety concerns encountered at a range of international recompression facilities when applying the Risk Assessment Guide for Recompression Chambers over a period of 13 years

by
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Declaration

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Abstract

Diving medical doctors frequently make use of Hyperbaric Facilities without fully realising their legal and ethical responsibilities towards the safety of their patients and their staff. Few have specific training in the technical or operational aspects of these facilities; this deficiency is exacerbated when these are established in remote areas. The potential dangers are real and the results can be devastating. Most current regulatory, manufacturing, safety and operational guidance documents are not flexible enough to be applied universally, nor do they offer practical guidance on the recognition and the mitigation of the unique and relevant hazards at a given facility. The goal of integrated safety is rarely achieved.

The Risk Assessment Guide (RAG) was developed by the investigator as a tool to qualify the actual safety status of a hyperbaric facility and to offer guidance on how to improve and maintain it. Although the RAG has been subject to extensive peer review and field implementation over the past 13 years, it has not been subject to scientific validation. Therefore, the objective of this thesis was to do so by (1) retrospectively reviewing the most common safety concerns affecting facility status as identified by the RAG; (2) using the data derived from the analysis to produce a predictive model of likely safety status for un-assessed facilities; and (3) consolidating the results in the form of specific recommendations to improve and maintain safety status.

Data collected from a consistent application of the RAG over a period of 13 years, covering 105 applicable facilities, was analysed to determine the common safety concerns, particularly those affecting safety status by means of a consolidated Risk Assessment Score (RAS). The RAS values permitted comparisons between the facilities assessed. The various factors associated with a higher RAS were determined by means of a multivariate regression. Thereupon, the most significant determinant factors were built into a predictive model for the likely safety status of an un-assessed facility. Finally, the most common safety concerns were identified and summarised so that medical practitioners are empowered to determine, improve and maintain the safety status of a given facility.

The conclusions of this project are that: (1) the RAG is an appropriate tool to assess facilities for risk elements relevant to their safety status while simultaneously filling the knowledge gaps to equip medical practitioners and staff to improve and maintain safety; (2) reliable predictions on unknown facilities can be made to provide medical practitioners with the necessary information on whether a given facility is appropriate for patient referral; and (3) the RAG is a suitable benchmark for determining hyperbaric facility safety; the review of its application has provided objective data that will permit the formulation of future safety guidelines based on empirical rather than arbitrary information.

Opsomming

Duikmediese dokters maak dikwels gebruik van hiperbariese fasiliteite sonder om die wetlike en etiese verantwoordelikhede ten opsigte van die veiligheid van hul pasiënte en personeel te besef. Weinig het spesifieke opleiding in die tegniese of operasionele aspekte van hierdie fasiliteite; hierdie tekort is gewoonlik erger in afgeleë gebiede. Die potensiële gevare is wesenlik en die gevolge kan verwoestend wees. Meeste van die huidige regulatoriese-, vervaardigings-, veiligheids en operasionele leidingsdokumente is nie buigsaam genoeg om in die algemeen toegepas te kan word nie. Hulle bied ook nie praktiese leiding oor die erkenning en die versagting van unieke en relevante gevare by 'n gegewe fasiliteit nie. Die doelwit van geïntegreerde veiligheid word selde bereik.

Die “Risk Asssessment Guide” (RAG) is voorheen deur die navorser ontwikkel as 'n instrument om die werklike veiligheidsstatus van 'n hiperbariese fasiliteit te kwantifiseer en leiding te bied oor hoe om dit te verbeter en in stand te hou. Alhoewel die RAG onderhewig was aan uitgebreide eweknie hersiening en praktiese uitvoering oor die afgelope 13 jaar, was dit nie voorheen onderhewig aan wetenskaplike validasie nie. Die doelwit van hierdie tesis is dus om hierdie te bewerkstellig deur (1) die mees algemene veiligheidskommernisse wat fasiliteitstatus beïnvloed, soos deur die RAG geïdentifiseer, retrospektiewelik te hersien; (2) die data wat deur die hersiening verkry is te gebruik om 'n model te ontwikkel vir onbeoordeelde fasiliteite, wat die waarskynlike veiligheidsstatus kan voorspel, en (3) die resultate te konsolideer in die vorm van spesifieke aanbevelings om veiligheidsstatus te verbeter en in stand te hou.

Die data wat ingesamel is deur die konsekwente toepassing van die RAG oor 'n tydperk van 13 jaar en wat 105 fasiliteite gedek het, is ontleed om die algemene veiligheidskommernisse, veral die wat die veiligheidsstatus beïnvloed, deur middel van 'n gekonsolideerde Risiko-assesserings waarde (RAW) te bepaal. Die duidelike en aangepaste RAW laat toe om vergelykings tussen die fasiliteite te tref. Faktore wat verband hou met 'n hoër RAW was deur middel van 'n meervoudige regressie bepaal. Daarna is die belangrikste determinante in 'n voorspellende model gebou om die waarskynlike veiligheidsstatus van 'n onbeoordeelde fasiliteit te bepaal. Ten slotte was die mees algemene veiligheidskommernisse geïdentifiseer en opgesom om sodoende mediese praktisyns te bemagtig om die veiligheidsstatus van 'n gegewe fasiliteit vas te stel, te verbeter en in stand te hou.

Die gevolgtrekkings van hierdie projek is dat: (1) die RAG 'n geskikte instrument is om fasiliteite te evalueer vir risiko-elemente wat relevant is tot hul eie veiligheidsstatus en terselfdertyd die kennisgapings te vul om geneeshere en personeel toe te rus om veiligheid te verbeter en in stand te hou; (2) redelik betroubare voorspellings oor onbekende fasiliteite kan gemaak word om vir mediese praktisyns die nodige inligting te verskaf aangaande die geskiktheid van 'n gegewe fasiliteit vir pasiënt-verwysing, en (3) dat die RAG 'n geskikte maatstaf is vir die bepaling van hiperbariese fasiliteit veiligheid. Die hersiening van die toepassing het objektiewe data voorsien wat die formulering van toekomstige veiligheidsriglyne, geskoei op empiriese eerder as arbitrêre inligting, sal toelaat.

Dedication

This thesis is dedicated to the advancement of diving and hyperbaric safety. As such it is dedicated specifically to the Divers Alert Network who embodies this vision and gave the entire undertaking both significance as well as opportunity.

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Dr Jack Meintjes has been a tireless supervisor with the right measures of continued encouragement, guidance, advice, insight and endless patience.

Dr Frans Cronjé has been a partner in this project over many years. After seeing the potential in my very first risk assessment report delivered in 1998, he launched me into the international arena in 1999 with motivation to write the guides. He has never ceased to encourage and inspire me to keep at it. This thesis is a testament to a partnership and friendship that goes beyond words.

No project of this magnitude, spanning more than 15 years, could have been possible without the unfailing support and understanding of my wife Karyn and children Gregory and Richard.

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Chapter 1: Background, introduction and literature review

Background

Hyperbaric facilities for the treatment of diving illnesses first appeared in historical recollections in 1885 during the tunnelling work being done under the Hudson River in New York. This was the first recorded successful use of pressure in the treatment of what was then known as "caisson's disease".[1] As the range of work under pressure expanded from compressed air caissons to professional compressed gas diving, therapeutic recompression facilities inevitably followed in its wake. However, apart from several ambitious "cure-all" efforts by medical doctors during the early years, it was really the work by German submarine and military diving divisions that spear-headed the development of Hyperbaric Facilities for the recompression of divers presenting with symptoms of decompression illness.[2]

Although demands for commercial diving continued to grow, the harsh conditions and primitive diving equipment did little to encourage diving as a sport. That was until the introduction of self-contained underwater breathing apparatus (SCUBA) by Jacques-Yves Cousteau who originally developed his famous 'demand valve' regulator for military applications during World War II. Suddenly diving was within reach of amateur enthusiasts and recreational diving received its initial kick-start in the late 1940's. Combined with the rapid growth of hyperbaric oxygen therapy from the mid 1950's, diver recompression facilities began to appear and spread around the world as the boom of air travel offered access to remote and exotic diving locations. This pursuit of unspoilt, remote dive destinations continues to this day. Consequently, many diving injuries occur in remote locations poorly prepared for these emergencies. Not infrequently the emotional impact of a severe case of decompression illness in these remote locations becomes the stimulus for setting up a local recompression facility. Often such facilities are built on impulse, outside the support of healthcare facilities, using rudimentary reconfigured military or commercial equipment, and with only volunteer divers as staff and variable medical coverage for support. The reliability and sustainability of these facilities is frequently dubious, the training frequently marginal, and the safety standards highly variable. These concerns were specifically mentioned at separate meetings (unpublished) of the Southern African Undersea and Hyperbaric Medical Association and the International Divers Alert Network. Concerns have also been expressed in the literature.[3, 4] For health professionals and diving safety organizations needing to refer injured divers to such facilities, it became essential to find a means of assessing the appropriateness of such recompression facilities for a given diving emergency. This need formed a major stimulus for the development of the Risk Assessment Guide.[5]

As evidence for the beneficial application of recompression therapy continued to increase, it eventually became 'standard practice' in commercial and military diving. Not surprisingly, as recreational diving took off, so did the need for recompression. In lieu of proper training and regulations, diving accidents were quite common in the early years. Eventually, industry standards, safety practices and formalised training for recreational divers developed organically around the world. Originally based on trial and error (experience) and tradition, arbitrary precautions and 'common sense' practices ultimately became more refined by the dissemination of medical information and standardised training. Still, injuries and breaches in safety have continued to plague the industry, prompting the development of ever more

specific safety practices and standards based on the chamber manufacturers' interpretation of the requirements set by the medical industry and regulatory authorities.

Even today, the interpretation of safety standards and how they translate to actual operational, training and safety practices remain alarmingly inconsistent across the globe[6]. Many countries have *partially applicable* standards and regulations in place, based on issues such as fire prevention, occupational health and safety, and pressure vessel design. However, these generic standards leave much to the imagination. Indeed, in the absence of an absolute need for them, surprisingly few countries have had the necessary incentive to develop effective regulatory standards and codes. Where needs have arisen, they have typically been in response to concerns about unsafe or unethical medical practices; a demand for fair economic enterprise; or sadly, often a catastrophic accident demanding statutory intervention. Even then, most guidance documents for safety in hyperbaric facilities were based on commercial and military diving. Their 'industrial' approach was usually inappropriate for patients (i.e. non-commercial or military divers) receiving medical treatments, since most patients – including injured recreational divers – are completely unfamiliar with recompression until they need it themselves. Moreover, most commercial and military facilities are not designed for clinical applications; even simple things like moving patients in and out of pressure locks can become a dangerous and backbreaking affair. It seems odd that the health and safety standards applicable to a recognised medical therapy in such regular use around the world would be so poorly defined. Yet they were.

In almost all countries, hyperbaric medicine (including recompression therapy for recreational diving injuries) is practiced by medical doctors. Of these, few are trained in the unique operational and technical equipment aspects required for safe and effective treatment. Relegating this responsibility to technical personnel or support staff without proper understanding or training has produced a false sense of security and ultimately resulted in several accidents – even in well-established medical Hyperbaric Facilities. Even as recently as 1997, an accident review of hyperbaric chamber fires reported that there were several cases where the responsibility for fire prevention was borne by people who were untrained or ill-equipped to do so.[7] Nevertheless, this gap in awareness, training and proper delegation of authority and responsibility remains unresolved. Various standards, guidelines and regulations now exist, but this does not translate into a proper risk assessment with identification and mitigation of structural and operational deficiencies. These remain prevalent, particularly in unregulated or remote settings.

Introduction to hyperbaric medicine & the risk assessment process

Terminology

Several terms are used in this thesis to describe the hyperbaric environment and variables related to risk and safety. In non-technical settings, many of these terms are used interchangeably or ambiguously. To avoid this, to ensure that this work is accessible even to those without a specific technical background, and to provide greater consistency, the following terms are defined here. The primary objectives are to prepare the reader in advance for the various instruments and metrics described elsewhere in the study and to carefully circumscribe the meanings assigned to them by the investigator. The descriptions are deliberately succinct and for the purpose of clarity and contrast; they are not comprehensive, nor do they necessarily represent all the legal applications for their use.

- Code:

  A document containing minimum requirements to be met in order to assure safe construction or operation of a hyperbaric facility. A code is usually produced with the intention of being enforced by a statutory body or agency; as such they are usually mandatory.

- Chamber:

  A term to denote a pressure vessel for human occupancy. Depending on its purpose, the following adjectives may be added: *hyperbaric*- (i.e., when used primarily for clinical hyperbaric oxygen therapy), *diving*- (i.e., when used for operational diving support primarily) or *recompression*- (i.e., when used for the treatment of injured divers primarily). Most chambers perform more than one purpose. The term *chamber* refers only to the pressure vessel itself, whereas *facility* is used to include all associated support equipment and staff.

- Hyperbaric Facility:

  For the purpose of this thesis, the term *hyperbaric facility*, is used throughout the text to identify the installation of a pressure vessel for human occupancy for medical purposes. This may include recompression treatment for injured divers or clinical hyperbaric oxygen therapy and encompasses all aspects of the facility, not only the pressure vessel.

- Guideline:

  A document primarily published through industry participation in the interest of providing *guidance* or *information*, rather than being considered as a mandatory instrument.

- Hazard:

  A potentially *harmful situation* or *agent*. Note that where a *specific hazard* introduces a *specific risk* at a *specific hyperbaric facility*, the term "*risk element*" (see below) or *relevant hazard* has been used to indicate this specificity. In the individual reports, the term "risk element" would therefore apply whereas in the collective findings these would be denoted as "hazards" with "risk element" in parentheses.

- Multiplace and monoplace:

  Terms referring to the hyperbaric chamber type or design. *Multiplace chambers* have multiple pressurised compartments and can accommodate multiple occupants. These chambers generally have the ability to transfer occupants either into or out of the chamber, while the treatment compartment is under pressure. They are pressurised with air and the patients breath oxygen through a mask, head-tent or endotracheal tube. The staff tending the patients breathe air. This introduces the risk of developing decompression illness for which precautions must be taken. The terms multi-lock or multi-occupancy are used interchangeably. *Monoplace chambers* are typically but not always pressurised with oxygen. As the name suggests, they contain only one occupant – the patient. They are technically easier to install and operate although the

use of 100% oxygen demands stringent safety precautions. The terms single-lock and single-occupancy are used interchangeably.

- Non Compliance (NC):

  The failure of a hyperbaric facility to have adequately addressed, mitigated or otherwise contained a *risk element* in terms of the Risk Assessment Guide at the time of assessment.[5, 8]

- Risk:

  The *likelihood* that *exposure* to a *relevant hazard* or risk element will lead to negative consequences.

- Risk score (RS):

  A term specifically developed for and defined in this thesis as meaning the risk (as defined above) weighted by the frequency and consequences of a given exposure to the relevant hazard or risk element. The RS represents a summation and consolidation of *the overall impact of a given non-compliance.* Although use of any relevant guideline or checklist might identify an NC, the actual impact on safety of a given NC can only be appreciated fully if the relevant hazard or risk element associated with the NC is factored into the assessment. The latter is the core objective for generating a RS: Essentially the RS provides a *safety impact factor* associated with a particular *non-compliance.*

- Risk Assessment Score (RAS):

  A term specifically developed for and defined in this thesis as meaning the *summation of all risk scores associated with individual non-compliances in order to provide a global reflection of the hyperbaric facility*.

- Risk element:

  A unique term created by the investigator to denote *specific hazards introducing risks* as they apply to the *actual* equipment, conditions or potential circumstances present at the *specific hyperbaric facility* being assessed *at the time of assessment*. In places it is used interchangeably with the term "*relevant hazard*" (see "hazard" defined above). In the context of a specific facility assessment, discovery of a *risk element* represents a non-compliance. In order to maintain consistency in the identification and categorisation processes, *risk elements* are sub-divided into fire, mechanical or health risks.

- Risk management:

  The deliberate and methodical *process* of *eliminating*, *mitigating* and *managing exposure to hazards*.

- Safe or safety:

  The classical meaning of the term *safety* implies the overall health and well-being of all staff, patients or other persons that may be present in the hyperbaric facility, as well as the integrity of the facility itself. In the context of this thesis, *safety* represents *a lasting state of variable duration* in which adverse incidents, accidents, damage, injuries, illness or fatalities to both people and property *are successfully avoided* by means of *appropriate precautionary measures*.

- Standard:

  A specification intended to be applied on a compulsory basis and seeking to ensure a safe outcome in the context of operational health and safety.

- Statute:

  A legal instrument, enacted by a national legal system in a sovereign country or entity, providing compulsory instructions with regard to health and safety.

- Sustainability:

  A determination as to whether a hyperbaric facility can continue to remain in operation indefinitely and be available to provide the defined scope of services as advertised or otherwise claimed.

- Utilization:

  The frequency of use, determined as number of patients treated annually at a hyperbaric facility, specifically including any form of hyperbaric oxygen therapy.

- User:

  The person or organisation that benefits either directly or indirectly from the utilisation of a hyperbaric facility.

Risk assessment for hyperbaric facilities

The risk assessment tool used in this study was developed by the investigator and first published as a "Risk Assessment Guide for Recompression Chambers" in 1998.[5] Its development was in response to the need expressed by a diving safety organization and the Southern African Undersea and Hyperbaric Medical Association (SAUHMA). The stated purpose was to guide medical doctors to practice hyperbaric and diving medicine in a way that is safe for both the medical staff working in the facility and the patients being treated there. The tool was designed specifically to be user-friendly for use by medical doctors. However, achieving this objective was not simple: Hyperbaric facility risk assessment is a foreign concept to most medical doctors and the assessment skills required fall outside the scope of conventional medical education. Nevertheless, as most countries consider the supervising medical practitioner to be the legal *user* and therefore responsible for the overall safety of the facility, it was essential to equip doctors to meet this responsibly of which many were completely unaware. The risk assessment tool achieves this by providing a quantifiable measure of the safety status of a given hyperbaric facility. Seen in the broader context of

diving medicine, this objective metric (1) engenders greater confidence for making referrals to such facilities; (2) affords greater confidence in the safety of the treatments facilities provide; (3) assures that all parties are knowledgeable about the reliability and availability of treatment facilities; and (4) empowers facilities to actively eliminate, mitigate or manage their risks. The net result is that both the doctors using and those referring to such duly assessed facilities would be in a better, safer and more defensible position for having assessed them objectively.

Literature review

The process of developing the "Risk Assessment Guide for Recompression Chambers" included an exhaustive literature survey to define current knowledge, to determine the knowledge gaps, to gather the relevant safety information and to compile these into one useable publication or guide.[5] The repositories for relevant information probed during this review included the following:

Maritime certification society rules

In the main, most facilities used for diving and hyperbaric medicine have been regulated, at least initially, by the commercial diving industry. A comprehensive series of guides and rules are routinely issued by organisations that insure the ships, vessels and platforms on which the diving and hyperbaric systems are installed. These systems actually become a significant part of the insured vessel and, as a result, these so-called "certification societies" have had to develop rules to cater for the hyperbaric and diving components. The following maritime certification society rules make specific provision for diving and hyperbaric systems; these were consulted to build the foundational knowledge base for Hyperbaric Facilities: Lloyd's Rules (UK)[9] , Det Norske Veritas (DNV) (Norway)[10], Germanischer Lloyd (Germany)[11], American Bureau of Shipping (ABS) (USA)[12], Russian Maritime Register[13] and Nippon Kaiji Kyokai (Japan)[14]. The focus of all of these publications is to ensure safety for the sea-going vessel from fire, pressure explosion and to establish equipment redundancy requirements.

Pressure vessel manufacture and insurance codes

The USA has been most proactive in taking significant steps very early on to facilitate the insurance of pressure vessels by requiring compliance with specific code rules. Since 1911, the American Society of Mechanical Engineers (ASME) code set has provided rules for pressure vessel design and pressure equipment construction.[15] These rules have evolved in line with modern materials & engineering practices. One particular challenge has been the need for introducing non-metallic components, such as windows or view ports, in pressure vessel design. View ports are required for lighting and visual contact with the occupants; they are subject to deterioration and vulnerable to damage. Often they represent the greatest potential weakness in the design of the pressure vessel and therefore receive significant attention in risk assessments. To solve the problem of non-metallic structural materials, the ASME established the Pressure Vessels for Human Occupancy (PVHO) standard in 1971.[16] The PVHO-1 standard then developed into a more comprehensive publication addressing piping systems and other PVHO requirements.[16] The initial focus of these publications was simply to ensure structural integrity. Later PVHO-1 did expand to include certain operational items, such as appurtenances, safety devices and support equipment.

Fire protection codes

Born out of the ashes of the Apollo 1 disaster, in which three astronauts lost their lives on the launch pad, the National Fire Prevention Association (NFPA) was established to prevent fires in the USA space exploration program. Following a similar disaster in an experimental hyperbaric facility at Brookes Air Force Base in San Antonio, the NFPA committee undertook to compile a safety standard for hyperbaric facilities.[17] The document has evolved through a series of updates and is now a well-known, leading industry standard to prevent fires in hyperbaric facilities. Although the primary focus is fire prevention, the document has inevitably taken on a certain amount of design, construction and operational content. The complete standard encompasses healthcare facilities in general.

Diving industry documents

The US Navy Diving Manual has been a repository for all their diving related equipment safety standards and procedures since 1956.[18] In conjunction with this, the US Navy Technical Manual for twin-lock recompression chambers, initially drafted in 1988, provides the hyperbaric facilities requirements for treating injured (navy) divers.[19]

Hyperbaric facilities codes and standards

Australia's contribution to the applicable hyperbaric codes and standards lay initially in their national standard AS 2299 (Occupational Diving).[20] During the period 1995 – 1998, the Hyperbaric Oxygen Therapy Facilities Industry Guidelines (HOTFIG) were developed by the Hyperbaric Technicians and Nurses Association (HTNA).[21] These were eventually absorbed during the development of the formal standard known as AS 4774-2 (Work in Compressed Air and Hyperbaric Facilities).[22]

European countries have provided a diverse and divergent series of guidelines. These have included the British Hyperbaric Association (BHA) code of practice[23]; the Italian National Institute for Occupational Safety and Prevention (ISPESL) guidelines[24]; and then later, the consensus recommendations contained in the European Committee for Hyperbaric Medicine (ECHM) safety document.[25]

In the USA, the Undersea & Hyperbaric Medical Society (UHMS) published guidelines for monoplace (i.e., single-occupancy) chambers in 1991.[26] This was followed by multiplace (i.e., multiple occupancy) chamber guidelines in 1994.[27] Both of these documents focused primarily on operational safety issues but with applicable references to the required equipment.

Manufacturing and testing standards and specifications

There are a range of general standards and specifications that provide guidance and requirements for materials, engineering practices, operating practices and testing regimens for sub-systems in hyperbaric facilities. These are published and maintained by organisations such as the American Society for the Testing of Materials (ASTM)[28-31], the Compressed Gas Association (CGA)[32], the International Maritime Contractors Association (IMCA)[33-36], the European Committee for Standardisation (CEN)[37], the South African Bureau of Standards (SABS)[38-44] and NFPA[45, 46].

South African statutes and acts associated with occupational health and safety, medical devices, and the practice of medicine

Finally, the statutory publications for South Africa were consulted, including the Occupational Health and Safety Act[47]; Medicines Control Act[48]; and Health Act[49] (later replaced by the National Health Act), for specific requirements pertaining to general safety that would apply to any hyperbaric facility. Although hyperbaric oxygen therapy represents the use of oxygen as a pharmaceutical agent to some extent, hyperbaric facilities are classified generally as medical devices in most countries. Diving regulations are generally inappropriate for clinical use. Medical supervision of hyperbaric oxygen therapy and recompression therapy provided outside of a commercial diving setting therefore typically falls in the category of the practice of medicine rather than diving.

The genesis of the Risk Assessment Guide

The Risk Assessment Guide was developed by the investigator in the mid 1990's. The objective was to coalesce the myriad of regulations, statutes, codes, and guidelines into a single, flexible, principle-driven approach to hyperbaric facility risk and safety. It had to be easily accessible to the average user and be applicable to a broad range of hyperbaric facilities irrespective of their geographic location. To achieve this, various current risk management practices were consulted. Some of these, such as the Australian Standard AS 4360, typically used refinement techniques to evaluate risk outcomes.[50] The assessment approach is referred to as a qualitative, semi-quantitative and a quantitative analysis. The Australian approach to safety in the design and construction of hyperbaric equipment was very influential in the initial development of the Risk Assessment Guide during the late 1990's. However, none of the above numerous document sources provided a step-by-step list of how to understand, manage and operate a hyperbaric facility so as to encompass all the aspects that pertain to safety.

Many scientific approaches for risk assessments exist that provide accurate, clinical and even quantitative assessments. There is also a plethora of standards, risk management procedures and guidance documents that provide and promote the use of risk scoring matrices. However, *relevance* is key when assessing hazards, and some of the greatest deficiencies in the copious reference materials were their disjointedness, limited contextual applicability or a complete lack of integration. Risk, hazard and safety are inter-related and any safety review must account for the potential interactions.

To overcome these deficiencies, a method had to be found to categorise the various *hazards* as being relevant – called *risk elements* in this thesis – as well as being able to assess their up- and downstream implications intelligently. By pursuing this objective, the Risk Assessment Guide was ultimately able to make provision for the *specific identification and assessment of relevant risks* as well as fostering overall and ongoing *maintenance of safety* for a given facility.

In order to develop the range of potential risk elements, the "Comparative Study of Risk Management Standards" provided an appraisal of a series of international and professional standards.[51] The overriding comment from this review was that for realistic outcomes to be achieved, the unique hazards had to be considered that applied to the specific environment being evaluated. Using this central tenet, the Risk Assessment Guide focused on the primary, *unique* hazard areas associated with hyperbaric facilities for which the three categories were

defined as *fire-*, *mechanical-* and *health* risks.[8] What makes the many relevant hazards unique is their simultaneous presence and potentially cumulative effects within hyperbaric facilities.

Although these three distinct categories of fire-, mechanical- and health risk are described in great detail in the Risk Assessment Guide, the actual challenge lay in determining their relevance by considering both the probability that a particular risk may lead to a safety breach as well as the potential impact of the breach. This was achieved by weighting the various categories and subcategories related to each, thereby allowing for relative sorting of risk assessment findings so that the most important ones could be identified. This is not proprietary information and is commonly referred to in occupational health and safety risk assessment ranking designs, such as those described by Donoghue[52] and others[53-56]. For example, the concept of *fire risk* is a clear and enduring determinant of safety in hyperbaric environments. As such it requires a weighting in addition to more traditional technical and operation risk scores. The *mechanical risk* category caters for hazards identified in the technical (structure) and 'reliability of operation' fields. The *health risk* category allows for a relative weighting to accommodate human interface, interaction and exposure hazards, medical interventions and all other operational or management actions.

The Risk Assessment Guide thus collates all the applicable information described above in order to enable a complete, comprehensive and totally applicable safety assessment on any type of hyperbaric facility. Importantly, unlike the common practice of blind compliance by means of a checklist provided by a specific standard or specification, the Risk Assessment Guide assesses the *actual risks* that apply to a *specific facility*. This unique approach is able to account for all aspects of system design and function of a given facility from the perspective of global safety integration, not merely an itemised review.

Applying the Risk Assessment Guide

Commencing in 1998, the Risk Assessment Guide was applied over a period of 13 years to a total of 105 facilities from around the globe. The scope of the assessments covered a wide range of facilities – from those located within developed countries with defined regulatory requirements to facilities located in remote regions where no national, regional or local regulations existed. Requests for assessment were motivated by different reasons. Remote and unregulated areas requested assessments in order to provide the medical doctors using these facilities with safety assurances and the necessary confidence that patients and staff would not be at unnecessary risk with the doctors bearing the legal burden for any complications. Those in developed areas sometimes needed to reassure hospital boards, medical protection organizations and even funders. As such, the scope of the assessed facilities was not only diverse, but it actually included the majority of global facilities eligible for assessment.

Comprehensive reports, which detailed all the safety risks and other concerns, were submitted following the assessment. For a number of facilities, second and even third reports were submitted (after re-assessment). All the reports contained a section with details on all non-compliances with the Risk Assessment Guide, as well as a list of recommendations for improvement of safety (where safety issues arose but that did not pose an immediate risk during on-going operations). These reports provided a helpful reference document to guide the facility on ongoing quality assurance and safety improvements; it drew attention to the areas of concern, and provided practical recommendations to address them.

Upon initiating these assessments, it soon became evident that there were a number of common areas of non-compliance affecting the safety status of the facilities. This information is entirely unique as there has never been a systematic review of hyperbaric facilities prior to this work. The UHMS only started its accreditation process for hospital-based facilities in the USA in 2001; to date, the UHMS has not reported on any of its collective findings. Therefore, the information contained in this thesis represents an invaluable resource: On the one hand it contains information from a sample of facilities that covers a cross-section of the total number of international hyperbaric facilities; and on the other it is made up of two thirds of the eligible hyperbaric facilities used in the treatment of injured divers (see study inclusion criteria). Until now, none of this information has been in the public domain. In fact, the literature review identified virtually a complete absence of data on risk assessment outcomes; associated or influencing factors; and primary safety factors influencing decisions by, or technical knowledge required for, medical practitioners at hyperbaric facilities. Without this information, neither medical practitioners nor emergency referral organisations are able to make informed decisions on patient referrals, nor to appreciate the liability for doing so. Both the original production of the Risk Assessment Guide as well as its application over 13 years were motivated by this – to empower medical practitioners and staff to assess and address risks and to fill the knowledge and competence gap to achieve this.

Upon completion, this thesis should provide those who are required to refer diving casualties to a hyperbaric facility with the necessary information and assurance of the essential safety status of the facility to guide appropriate decisions. Conversely, for those who serve injured divers at these facilities, this work will provide a tool for improving and maintaining the safety status of their facility in order to respond to these referrals in an appropriate and confident way.

Study aim and objectives

The main aim of this study was to review the data generated during the application of the Risk Assessment Guide in order to:

- retrospectively review the most common safety concerns affecting facility status as identified by the Risk Assessment Guide so as to:
    - determine a *risk score* for *each risk element* and to rank them by importance;
    - determine a *risk assessment score* for *each facility*, based on the risks associated with all the findings at the facility so as to rank facilities' risk standings relative to other facilities; and
    - identify the leading factors determining the risk scores and risk assessment scores.
- to consolidate the results derived from the analyses to produce specific recommendations to improve and maintain safety status.

In the course of the review, it became evident that a number of associated factors varied significantly between facilities. This resulted in the following objective being added retrospectively:

- to use the data derived from the analysis to produce a predictive model that allows the risk profile of a facility to be predicted based on knowing the associated factors.

Chapter 2: Study methodology

Study design

The aim and objectives of this study were realized by performing a retrospective review of the risk assessment reports of recompression facilities that had been assessed over the previous 13 years (1998 to 2011).

Study setting

There are approximately 750 international hyperbaric facilities that are potentially available for diver recompression treatment. This estimate is based on a physical review of the hyperbaric facilities listed by the Divers Alert Network of America and the Divers Alert Network of Europe, as captured in their "Medical Services Call Centre Database". The list contains facilities that have either participated previously in treating divers referred to them by Divers Alert Network or those who have registered themselves specifically for this purpose. However, only a minority of these facilities were appropriate for assessment using the Risk Assessment Guide: Most of these facilities are primarily established for clinical hyperbaric oxygen therapy for non-diving related conditions; diver treatments are secondary and usually incidental to their other activities. Other facilities fall within jurisdictions where strict accreditation or other regulatory controls are well-established, thereby negating the need to perform further assessments. Some hyperbaric facilities belong to naval or other military facilities that do not sanction civilian assessments or interference with their strictly military protocols – even though such chambers might accept an injured civilian diver in an extreme emergency.

By eliminating the clinical hyperbaric oxygen facilities, those strictly accredited and the military facilities, a total of 160 international hyperbaric facilities remained where the treatment of injured recreational divers was their primary scope of services. These facilities were also those that would be eligible for assessment under a global chamber safety improvement program. Out of these 160 potential hyperbaric facilities, a total of 105 were inspected, assessed and reported on by the investigator between 1998 to 2011 – a period of 13 years. These facilities were located in areas at or near diving regions around the globe, stretching east as far as Papua New Guinea; west as far as the Galapagos Islands; north as far as Ireland; and south as far as South Africa.

The data, in the form of 105 initial, comprehensive risk assessment reports, personal notes, documentation and photographs, had been collected through personal on-site visits. These included visual inspection of all the facilities, a review of all applicable documentation and interviewing of the facility personnel.

In several cases, based on utilisation as well as requests by facility owners or medical directors, follow-up visits were undertaken and revised reports were issued. These were not included in the analysis.

The majority of the facilities were used by medical practitioners who primarily provided hyperbaric treatments to injured recreational divers. The same facilities were also used as referral centres by, amongst others, diving safety organizations like the Divers Alert Network.

Study "participants"

The "participants" for this study were the 105 assessed hyperbaric facilities as represented by their respective risk assessment reports.

Inclusion criteria

All the hyperbaric facilities that were assessed by the investigator were included in the analysis. Only the initial assessment reports were used in the analysis of data. Subsequent or follow-up visits included improvements undertaken as a result of the initial risk assessment performed and were therefore excluded. Initial assessments thus preserved the actual status prior to any education, guidance or instruction provided. The original assessment notes, photographs taken of the facility and photocopies of equipment certification documentation were used where any data was unclear or where clarification of the condition of the facility was required.

Exclusion criteria

The only exclusion condition was that no follow-up risk assessment reports were utilised in the data capturing or analysis. Therefore the analysis did not account for facilities closing, changes in management, ownership, types or numbers of recompression chambers in use, scope of services, or staffing, whether facilities were deemed safe for use or not, or any other qualitative or quantitative findings raised during assessments.

Data sources

All data was extracted from the original risk assessment reports compiled on completion of the on-site evaluations, together with accompanying photographs taken to record the actual equipment, and any notes used to record safety concerns.

Variables

The actual non-compliant (NC)[†] issues, as classified in the Risk Assessment Guide and listed in table 1, were the primary data collated and analysed.[5, 8] These had been identified during the visits to facilities and are described at the back of each facility's risk assessment report.

These NC's were categorized and captured by the investigator. For each facility assessed, the absolute number of NC's identified at the facility was captured. These were then used to calculate a *risk assessment score* for each facility.

The following variables were also collected from the risk assessment reports, notes, facility documentation and photographs. These variables represented relatively objective information about the facility and its operations. They were assessed as potential predictors for risk assessment scores to be employed subsequently in the development of a predictive model:

- The geographic location worldwide (country or region);

[†] A non-compliant (NC) issue arises where a hazard is identified as being a potential risk at a facility and is not suitably addressed, mitigated or contained. A NC is also referred to as a "Risk Element" or an element of concern in the context of this study.

- The year that the facility was assessed for the first time;
- The operating age or time that the facility had been in operation (in years) as at the date of the initial assessment, classified as less than one year, between one and five years and more than five years;
- The type of treatment protocols provided, recorded by reference to internationally-accepted treatment tables (USN TT5, TT6, TT6A, Comex 30), which provide information on treatment pressures and therapeutic gases utilised;[57, 58]
- The type of chamber installed, categorized as monoplace (single lock) or multiplace (multi lock chambers);
- A referral rating, categorized from A to F, which is based on type of service and whether the facility is suitable for referral. Together with the type of treatment protocols available, this will aid categorisation of facilities for medical referral purposes.

  A: Hospital-based facilities, with in-chamber advanced life support capabilities.

  B: Hospital-based facilities with no in-chamber advanced life support capabilities.

  C: Non-hospital based facilities allowing treatments at absolute pressures exceeding 300kPa.

  D: Non-hospital based facilities allowing oxygen treatments only.

  E: Facilities where a restriction applied due to safety concerns and referral to such facilities were not recommended at the time of assessment.

  F: Facilities that were not considered safe at the time of the assessment where no treatments should be provided.
- Availability of services for diving emergencies, categorized as either during office hours only or with after-hours support or on a 24/7 basis. (Some facilities were closed at the time of the assessment, either due to management changes, not yet being operationally ready to accept patients, or closed due to technical issues.);
- The utilisation of the facility divided into three categories, namely low (less than five patients per year), normal (between five and fifty patients per year) and high (more than fifty patients per year);
- The system reliability, dichotomised as yes or no, based on the evidenced maintenance regimen. A well-structured and effective maintenance program was considered as sufficient to ensure a reliable facility.
- Sustainability of the facility, dichotomised as yes or no, based on a combination of funding-stream (stable income from insurance companies or paying patients), stability of ownership (lack of frequent changes in ownership or management) and the permanence of staff (low staff turn-over profile).
- The degree of medical supervision, based on the presence of an appropriately trained doctor, categorized as either on a full time, on-call or completely absent basis;
- The staff skillset, categorized as being formally certified to local/international standards (formal), trained in-house (informal), or with no acknowledged training (not trained).

Processing of data

In order to calculate the frequency of NC's across the spectrum of facilities assessed, all NC's were reported on using a simple *1 = yes* or *blank = no* notation. For greater consistency, only absolute values were applied; no degree of mitigation was captured. For example, in situations where the lack of a specific item could be mitigated by a specific operational procedure or by addressing the risk on a temporary or permanent basis, this fact was disregarded in determining the risk scores. Similarly, to minimise the Hawthorne-effect, even simple remedial actions that were proposed and implemented by the staff during the course of the assessment (e.g., applying physical work-arounds, procedural changes, awareness education and even removal of equipment, materials or practices), were disregarded for greater consistency in determining the baseline risk score. Only the raw data were used to determine the relative spread across the spectrum of participants. The number of facilities that presented with a specific NC was divided by the total number of facilities evaluated, thus providing a percentage of facilities that did not comply with a specific item.

The objective of the study was to make a *semi-quantitative* assessment of risk for the purpose of comparison design.[50] Thus, in order to rank the NC's across the participant spectrum, the *risk score* was used rather than *frequency of occurrence*. In this way the relevance of a particular NC to the overall safety could be determined systematically by applying an appropriate weighting system. In other words, by multiplying the *frequency of occurrence* with the *likelihood of occurrence of a safety breach* given a particular NC with the *severity or consequence* of such an event, the potential impact of the NC on overall safety could be consolidated into a single risk score.

In order to determine the *likelihood of occurrence of a safety breach*, given a particular NC, a 5-point Likert scale was used for each of the three main hazard groups (i.e., fire-, mechanical- and health risk). This probability weighting provided a relative measure that could be applied consistently to all participants. In the same way a second 5-point Likert scale was used to provide a relative indication of the *potential severity* of occurrence of a safety breach resulting from exposure to a particular hazard.

Some references, such as the US Department of the Interior, employ a categorical Risk Assessment Code designation by means of an alphabetical letter.[56] However, this was not suitable for the purpose of comparative analysis, nor would it have permitted the formulation of a predictive model. Thus, even though the weighting was a relative measure, based on expert opinion, the ultimate RS is understood to be a relative value – permitting comparisons between risk elements – rather than being an absolute one. As such, a numerical value output has greater utility for the purpose of comparisons and to allow numerical sorting. Thus, even though risk scores are inevitably somewhat subjective in nature, the investigator provided consistency by (1) assuming in each case that the severity represented the likely worst case in every event, and (2) by avoiding any amelioration or mitigation in determining severity when applying this score to any of the NC's.

Appendix A displays the basic scoring system that was adopted and utilized during processing of the raw data.

The risk elements (i.e., the relevant hazards) were also subdivided into three subsections, viz. technical (mechanical & electrical), managerial (administrative), and maintenance hazards. The technical hazards represented *engineering* areas of risk; managerial represented the

operational risk of the facility; and maintenance covered the risks associated with any lack of *continuous attention to equipment and facilities*.

These subsections were added to differentiate between purely technical issues and those introduced by the human interface. In general, Hyperbaric Facilities that are designed, built, installed and commissioned according to the various mandated standards [22, 59, 60] and guidance documents [26, 27, 61], are unlikely to be rendered unsafe through purely technical means.

Study size and sample size calculation

The full list of available risk assessment reports for the facilities was reviewed for inclusion. As only the facilities that offered recompression treatment of injured divers as their primary service had requested risk assessment, no facilities were excluded from the sample.

Quantitative variables

The mean number of NC's (with standard deviations) and the median number of NC's (with interquartile ranges) are used to describe the sample statistics. Population values are estimated by means of 95% confidence intervals.

For each country in which facilities were assessed, the mean number of NC's for all facilities in that country, as well as the mean and median RAS are presented.[‡]

Statistical methods

Each NC item is described in terms of the absolute number and as a percentage of facilities found to be non-compliant to that item. Population estimates for these values are indicated by means of 95% confidence intervals.

Likewise, for each NC item a risk score[§] was calculated by multiplying the frequency of occurrence with the weighting system as described in the section ("processing of data") above. The population risk scores associated with each item are again indicated by means of 95% confidence intervals.

The Risk Assessment Score (RAS) was then determined for each facility: The weighted scores for each of the NC's at a specific facility were collated and summed into a total RAS for each individual facility and the population data again shown as 95% confidence intervals.

In order to evaluate the association of individual factors (e.g., demographic factors such as region; treatment pressure; presence of a medical practitioner; etc.) with the RAS across the sample, the mean RAS's were compared between the different subgroups representing each of these factors. To avoid circular reasoning, the individual factors associated with RAS scores were not part of the risk assessment scoring system; they were descriptive factors

[‡] In most countries only a single facility was assessed. It is therefore not considered appropriate to estimate population values (e.g. 95% confidence intervals) for the different countries, i.e. it is not considered appropriate to extrapolate population values from a single data point.

[§] For the sake of clarity, it is worth stating again that: a risk score (RS) is the sum of all weighted NC's per risk element or concern; a RAS is the sum of all weighted NC's per facility.

related to the nature, staffing, and practice patterns of the facility. When only two sub-groups existed within each variable, the F-test was used for comparison of variances and the t-test was used to compare the mean RAS's (assuming equal or unequal variances as determined by the F-test). However, if one of the sub-groups contained less than 30 observations, the Wilcoxon rank sum test was used. When more than two sub-groups were compared, the Analysis of Variance for independent samples was used to compare the mean RAS's (or the Kruskal-Wallis test when individual sub-groups contained less than 30 observations). A p-value <0.05 was considered statistically significant. All these analyses were performed using the PhStat2 add-in system (version 2.5.0) for Microsoft® Excel®.

After describing and analysing the association of individual factors (variables) with the RAS, a multiple linear regression analysis was used to derive a linear equation to predict RAS, based on using the associated factors as predictors.

The final predictive model was built using manual intelligent modelling and likelihood ratio tests. Factors were introduced into the model one at a time starting with the variable considered to be the most important from a practical clinical point of view. Factors were removed from the model if they did not contribute to an increased R-squared and the likelihood ratio test was insignificant. This way the minimum number of significant determining factors could be selected. The final model was tested by once again adding the excluded variables one at a time and testing their significance, using likelihood ratio tests. This analysis was performed using Stata (StataCorp) version 12.1. A p-value <0.05 was considered as statistically significant.

Ethical considerations

This study was approved by the Health Research Ethics Committee (HREC) of Stellenbosch University (reference number: N11/08/263). The following ethical considerations were kept in mind throughout the conducting of this study:

Beneficiation – the study participants (implying the individual facilities that were assessed and reported on) did not benefit directly from participation in this study although they had benefited greatly from the original assessments and reports from which the data was derived. In addition, there are significant benefits to the hyperbaric industry as a whole as a result of this study: Identification of common risks can prioritise the development of detailed guidance documents leading to safer treatment facilities worldwide. Also, the identification of factors commonly associated with high risk facilities will indicate the areas of highest priority to make individual facilities safer.

Non-maleficence – no harm or detriment is expected to arise through the performance and publication of this study. The results of the initial assessments were shared only between the hyperbaric chamber facilities and the diving safety organisation who jointly requested the assessment. This study is retrospective in nature and did not identify any facilities by name.

Confidentiality –the names of the facilities used during the initial and follow-up assessments are not disclosed in the study. Traceability was achieved using a simple number reference to a password-protected spread-sheet, to which only the investigator had access. Only the general geographic location is indicated in the data collection form and reported as such.

Non-discrimination – there is no discrimination against any facility, staff members or industries served. In most cases, facilities were either owned by international organisations,

by local diving industries, or by local medical establishments. Staffing is usually a combination of local and international (ex-pat) members. Regional locations do not determine the nationality of the owners or operators. Divers travel internationally from Europe, the United States and practically all countries across the globe. There is no recording of ethnicity, culture, religion, financial means, community standing or individual abilities. Since none of these factors have ever been identified as having a direct bearing on the safety of a facility, these were not captured.

Informed consent – the initial and follow-up assessments were all done at the specific request (and thus with the implicit consent) of the facility being assessed. The assessment reports have also been shared only with the specific facility and the diving safety organization involved; not with any third party. Obtaining informed consent for this analysis from individual facilities that were assessed over a period of 13 years proved to be completely impractical: several facilities had since closed, others had changed hands, and a number of them had been rebuilt or re-structured. In many cases, the original staff members have left including the persons who had requested the original assessment. The investigator also ensured that no personal, business, operational or financial information of any facility was exposed in this study. As a result, the HREC approved a waiver of informed consent to conduct this study.

Budget and funding resources

The original development of the Risk Assessment Guide by the investigator was self-funded with modest sponsorships from a South African hyperbaric management company and an international diving safety organization. The 105 on-site assessments and reports, on which this study was based, were also performed by the investigator. These assessments, undertaken over a period of 13 years, were funded by the individual facilities and the international diving safety organization. This study required the personal time and resources of the investigator only. Resources such as computer-time, printing, internet access, literature resources and telephone access were borne by the investigator. These were minimal, as was expected.

Chapter 3: Results

General

Out of a total population of 160 hyperbaric facilities, 105 (66%) were assessed and therefore eligible for inclusion in this study. The assessments covered a total of 42 countries that are listed in Table 3 (in alphabetical order). No eligible facilities were excluded from the analysis.

No data gaps appeared during the extraction process that could not be interpreted or retrieved from photographs, assessor notes or facility manuals. The variables for all participants could be collated with the highest degree of accuracy.

The results are reported with the risk scores (in terms of the individual hazards identified at the facilities) and then as risk assessment scores applicable to the remaining variables.

Risk assessment scores of individual risk element

The Risk Assessment Scores (RAS's) from the study are presented in the following tables using the variables and the weighted results detailed in the study methodology. Table 1 contains the relevant hazards (risk elements), with the total number of non-compliances (NC's) to the Risk Assessment Guide (RAG) across the total number of facilities (n=105), the frequency of occurrence as percentages of the total number of facilities, and the risk score (RS).

The relevant hazards are listed in order of magnitude of RS: from the highest score – the highest safety concern – through to the lowest score.

Table 1: Hazards (risk elements) determined by means of non-compliance to the RAG

	NC's			RS	
Relevant hazard description (risk element)	**N**	***f* (%)**	**95% CI**	**Value**	**95% CI**
Safety drills not practiced	89	85	78 - 92	33	30 - 36
Alternative breathing gas for operator - not provided for	91	87	80 - 93	32	30 - 34
Emergency operating/medical procedures un-documented	82	78	70 - 86	31	27 - 34
Maintenance system absent, inadequate or inappropriate	69	66	57 - 75	28	24 - 32
Leak testing not done	74	70	62 - 79	27	24 - 31
Air supply analysis or quality control lacking	85	81	73 - 88	27	24 - 29
Particle filters before regulators absent	85	81	73 - 88	27	24 - 29
Standard operating procedures not documented	68	65	56 - 74	25	22 - 29
Line isolation monitoring not installed	98	93	89 - 98	25	24 - 26
Oxygen cleaning procedures not in place	100	95	91 - 99	25	24 - 26
Operator check lists inadequate or lacking	65	62	53 - 71	24	21 - 28
Fire suppression system for chamber- testing inadequate	84	80	72 - 88	22	20 - 25
Dual shell valves or shell valves lacking	73	70	61 - 78	22	19 - 24
Safety valve checks & testing obsolete	73	70	61 - 78	22	19 - 24
Facility manual with policies inadequate or lacking	101	96	93 - 100	21	20 - 22

	NC's			RS	
Relevant hazard description (risk element)	**N**	***f* (%)**	**95% CI**	**Value**	**95% CI**
Management audits & control lacking	101	96	93 - 100	21	20 - 22
Training & certification inadequate or inappropriate	46	44	34 - 53	21	16 - 25
Ground fault or earth leakage system not installed	69	66	57 - 75	20	18 - 23
Written appointments lacking	86	82	75 - 89	20	18 - 21
Emergency chamber lighting lacking	71	68	59 - 77	19	16 - 21
Wiring inappropriate or messy	54	51	42 - 61	19	15 - 22
Oxygen analyser calibration missing	74	70	62 - 79	18	15 - 20
Power supply to chamber not ungrounded	68	65	56 - 74	17	15 - 20
Flexible hose maintenance neglected	53	50	41 - 60	17	14 - 20
Alternative breathing gas (occupants) not provided for	64	61	52 - 70	16	14 - 19
Back-up communicator absent	48	46	36 - 55	16	12 - 19
PTFE[1] tape inappropriate	95	90	85 - 96	15	14 - 16
Anti-suction devices missing or not installed	51	49	39 - 58	15	12 - 18
Safety valve for treatment depth not installed	91	87	80 - 93	15	14 - 16
Chamber escape not possible	89	85	78 - 92	14	13 - 16
Particle filters need to be cleaned	87	83	76 - 90	14	13 - 15
Viewport safety concerns (certification, age or type)	52	50	40 - 59	14	11 - 17
Gas cylinder security compromised	30	29	20 - 37	13	9 - 17
Fire alarm not provided for	80	76	68 - 84	13	12 - 14
High pressure gas safety valve absent on regulator	40	38	29 - 47	13	10 - 16
Labelling of chamber components inadequate	40	38	29 - 47	13	10 - 16
Air supply redundancy inadequate (insufficient gas)	52	50	40 - 59	13	10 - 15
Back-up power missing or inadequate	42	40	31 - 49	13	10 - 16
Chamber grounding not in place	50	48	38 - 57	12	10 - 15
Oxygen supply quality control inadequate	58	55	46 - 65	12	10 - 14
Caisson gauge lacking	48	46	36 - 55	11	9 - 14
Contamination of oxygen BIBS[2] (air not O_2 compatible)	40	38	29 - 47	11	9 - 14
Fire suppression system (chamber) – no water filter	42	40	31 - 49	11	9 - 14
Gas supply check valves not installed	34	32	23 - 41	11	8 - 14
Lubricants used on equipment inappropriate	34	32	23 - 41	11	8 - 14
Closed-circuit television missing	37	35	26 - 44	10	7 - 12
Safety valve on chamber lacking or incorrectly set	22	21	13 - 29	9	5 - 12
Room fire detection, signage and fire doors lacking	52	50	40 - 59	8	7 - 10
Compromised air intake (risk of contamination)	25	24	16 - 32	8	5 - 11
Oxygen & electricity exposed in panel (fire hazard)	40	38	29 - 47	8	6 - 9
Discrete communicator absent	57	54	45 - 64	8	6 - 9
Oxygen isolation valve absent (zone valve)	57	54	45 - 64	8	6 - 9
Pressure vessel testing after installation not done	30	29	20 - 37	7	5 - 10
Gauge calibration outdated or lacking	70	67	58 - 76	7	6 - 8

	NC's			RS	
Relevant hazard description (risk element)	**N**	***f* (%)**	**95% CI**	**Value**	**95% CI**
Workshop/area inadequate	28	27	18 - 35	7	5 - 9
Oxygen sample points inadequate	24	23	15 - 31	6	4 - 9
Service lock interlock absent	24	23	15 - 31	6	4 - 9
Patient indemnity form lacking	47	45	35 - 54	6	5 - 8
Bilge cleaning lacking (dirt & health hazard)	16	15	8 - 22	6	3 - 9
Exhaust gas outlets not secure	39	37	28 - 46	6	4 - 7
Piping materials unsuitable	12	11	5 - 18	5	2 - 7
Safety valve flow capacity inadequate	11	10	5 - 16	4	2 - 7
Pressure vessel certification lacking or inappropriate	17	16	9 - 23	4	2 - 6
Room fire extinguishers lacking	26	25	17 - 33	4	3 - 6
Oxygen analyser alarm needed (no high level alarm)	19	18	11 - 25	4	2 - 5
Connectors inappropriate for application	11	10	5 - 16	3	1 - 5
Oxygen analyser not installed	12	11	5 - 18	3	1 - 5
Clothing control not suitable	18	17	10 - 24	3	2 - 4
Fire suppression system for chamber - absent or lacking	19	18	11 - 25	3	2 - 4
Exhaust gas dumped into the chamber room	12	11	5 - 18	3	2 - 4
Switches installed not appropriate	10	10	4 - 15	3	1 - 5
Bilge inspection lacking (corrosion or damage)	9	9	3 - 14	3	1 - 4
Back pressure regulators lacking	11	10	5 - 16	3	1 - 4
Hearing/noise protection needed	18	17	10 - 24	2	1 - 3
Glycerine filled pressure gauges used	7	7	2 - 11	2	1 - 4
Chamber flooring inappropriate (fire or slip hazard)	8	8	3 - 13	2	1 - 4
Oxygen supply & back-up volumes inadequate (for Tx)	11	10	5 - 16	2	1 - 3
Air conditioning in room or chamber inadequate/absent	12	11	5 - 18	2	1 - 3
Oxygen storage in room inappropriate	8	8	3 - 13	1	0 - 2
Fire escape from room restricted	7	7	2 - 11	1	0 - 2
Electric motors in chamber not appropriate	2	2	0 - 5	1	0 - 1
Floor cleaning compound inappropriate	1	1	0 - 3	0	0 - 0
Mean values:	47	45%	39 - 51	12	10 - 14
Standard deviation:	29	28%		9	
Median value:	47	44%		11	
IQR (Q3 – Q1)	52	49%		14	

[1] PTFE: polytetrafluoroethylene, referred to as Teflon® or PTFE tape. Oxygen applications require this product to be degreased and compatible for use with oxygen, in order to minimise the risk of fire.

[2] BIBS: Built-in-breathing-system, referring to the equipment used to provide therapeutic gas to the chamber occupant and, usually, to expel exhaled gas outside of the chamber.

Table 2 indicates the relevant RS values for each of the three risk element subdivisions -- Technical, Management and Maintenance. The values for all relevant hazards are also reflected, consistent with Table 1 above.

Included are the mean RS values for all the relevant hazards (risk elements) per subdivision, together with standard deviations, as well as the computed median values and interquartile ranges.

Table 2: Risk Score (RS) values for the three main risk element subdivisions

	Hazards (n)	Mean RS (SD)	Median RS (IQR)	95% CI
Technical hazards (mechanical & electrical)	62	10 (7)	9 (10)	8 - 12
Management & administrative hazards	10	16 (10)	21 (5)	9 - 23
Maintenance hazards	10	17 (9)	18 (16)	10 - 23
ALL HAZARDS	82	12 (9)	11 (14)	10 - 14

Figure 1 below illustrates the nature of the distribution of the RS values around the mean value of 12 (SD ±9).

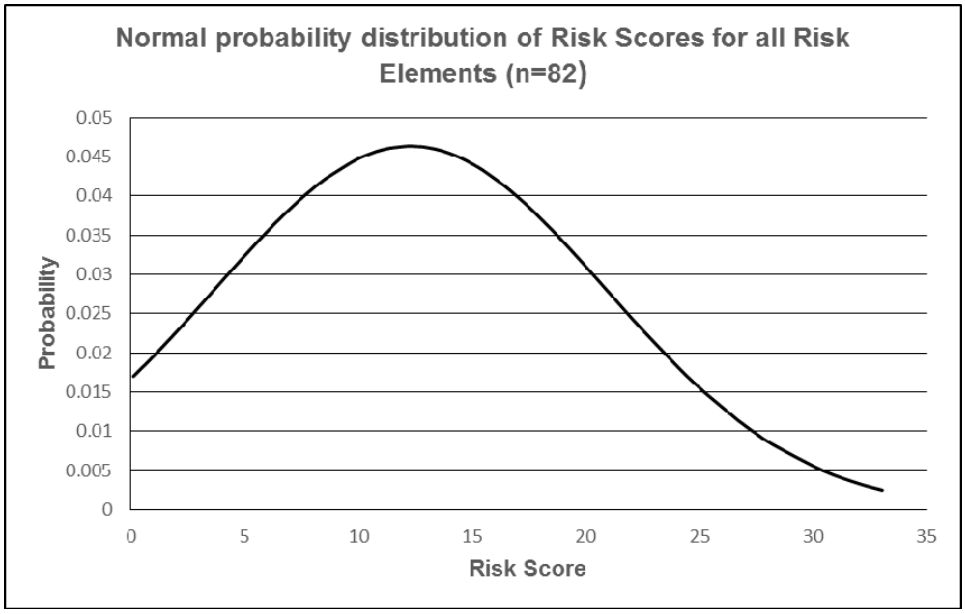

Figure 1: Normal probability distribution of risk scores for all risk elements

Associated factors

The descriptive variables that were used in the RAS association analysis, extracted from the assessment reports, are summarised below. Table 5 below contains a summary of all the data used to describe the variables.

Region:

Table 3 below provides the computed values for NC and RAS values for each country containing one or more facilities. For the purpose of comparing facilities by region, the NC values listed are mean values for all facilities within that country. Similarly, the RAS values include both mean and median values for the facilities in the specific country.

Table 3: List of countries where facilities were assessed

Country*	**No. facilities**	**NC_{Mean}**	**RAS_{Mean}**	**RAS_{Median}**
Bahamas	2	44	702	702
Belize	1	27	506	506
Bermuda	1	25	436	436
Bosnia	1	54	849	849
Brazil	5	44	713	742
Canary Islands	4	46	775	761
Cayman Islands	2	25	436	436
Colombia	1	58	866	866
Costa Rica	3	24	859	859
Croatia	4	24	414	441
Cyprus	4	34	599	668
Dominican Republic	3	49	804	811
Egypt	9	44	750	764
Ecuador (Galapagos)	1	41	735	735
France (Reunion)	1	24	435	435
Germany	1	48	787	787
Honduras	2	39	654	654
Hungary	1	17	318	318
Ireland	2	34	471	471
Israel	1	34	579	579
Italy	1	25	366	366
Jamaica	2	51	822	822
Madeira	1	27	504	504
Maldives	7	37	630	644
Mauritius	1	32	610	610
Mexico	5	45	717	748
N. Antilles	5	40	685	736
Namibia	1	9	185	185
Panama	1	25	440	440
Papua New Guinea	1	35	597	597
Poland	1	14	216	216

Country*	No. facilities	NC_{Mean}	RAS_{Mean}	RAS_{Median}
Portugal & Azores	3	30	534	492
Serbia	3	38	640	559
Seychelles	2	39	679	679
South Africa	7	20	356	277
Switzerland	2	39	672	672
Tanzania (Zanzibar)	1	19	309	309
Thailand	2	31	543	543
Turkey	3	46	760	730
Turks & Caicos	1	28	503	503
UK Channel Islands	1	21	392	392
USA & USVI	2	40	698	698
West Indies	2	49	783	783
Total	105	3855	-	-
Mean (total)†	-	37	619	-
Standard deviation	-	12	188	-
Median (total)†	-	38	-	680
IQR (Q3 – Q1)	-	18	-	259

*The term "Country" is sometimes used loosely to include self-determining island regions.

† These two computed values provide average and median values for the entire data set, for all 105 facilities. The tabulated RAS mean and median values are determined per country.

The global RAS for all facilities yielded a mean value of 619 (95%CI = 583 – 656).

Year assessed:

To obtain a meaningful analysis of mean RAS scores by year, those years with single assessments and those with no assessments were excluded from the analysis. Only one facility was assessed in 1998 and in 2000, yielding RAS's of 203 and 185 respectively. No facility was assessed in 1999. The remainder of the data are contained in Table 4. There is no statistically significant difference in the mean RAS of facilities when considering the year (2001 through 2011) of assessment (p=0.083).

Table 4: Number of facilities assessed each year (2001 – 2011)

Year of assessment	No. facilities assessed
2001	2
2002	9
2003	7
2004	9
2005	12
2006	12
2007	13
2008	18
2009	11
2010	4
2011	6

Figure 2 below depicts the RAS for facilities assessed by year.

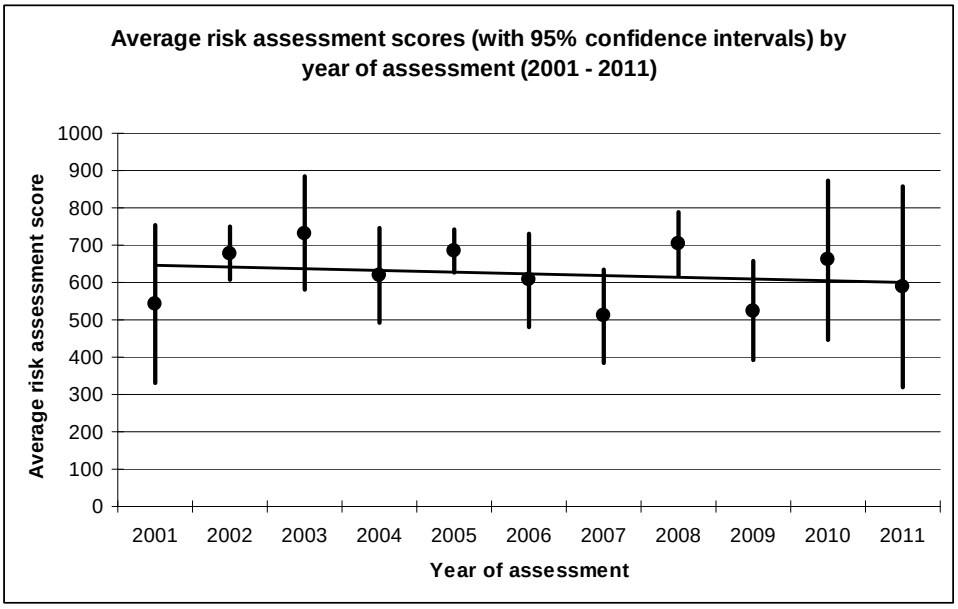

Figure 2: The average RAS of facilities assessed each year

Operating age:

Based on population trends, the number of years that the facility had been in operation as at the date of the initial assessment was indicated in three classes: *< 1 year*, between *1 and 5 years*, and *> 5 years*. There seemed to be a positive association between the average RAS and the duration of the facilities' operations. However the average RAS in these three classes did not differ significantly (p=0.117).

Figure 3 displays the relationship between the RAS and the facilities' operating age:

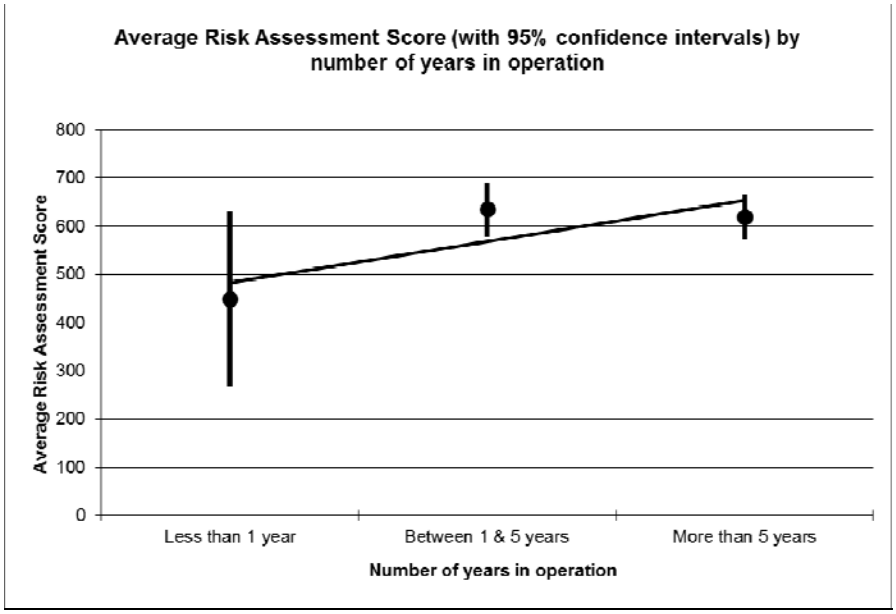

Figure 3: The average RAS by operating age

Type of treatment protocols:

Treatment protocols have pressure and time dimensions. The pressure component carries greater significance in terms of risk as the complexity of treatment and the potential range of complications increase proportionally. Therefore, treatments were classed according to maximum pressure (depth) and three pressure regimes were recorded: *up to 300 kPa*, up to *400 kPa* and up to *600 kPa* (all indicated as absolute pressures). There is a trend indicating an increased average RAS with an increase in maximum treatment pressure offered by the facility. The 95% confidence intervals for the average RAS in these groups overlap. However, the p-value (using non-parametric methods as is appropriate) is significant at 0.020.

Figure 4 depicts the relationship between the RAS and the maximum pressure of the treatment tables provided by a facility.

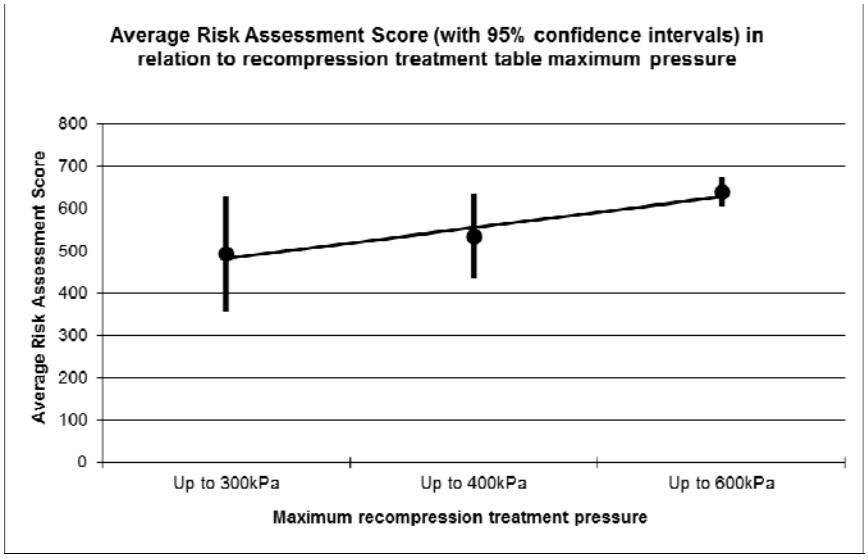

Figure 4: The average RAS by maximum treatment depth of the facility

Type of chamber:

There is a statistically significant difference between the RAS for *monoplace* (i.e., single lock / occupancy) and *multiplace* (i.e., multi lock / occupancy) chambers (p=0.005). Monoplace facilities are typically simpler to operate. The average RAS for multiplace chambers is 641 (95%CI = 607 to 675), higher than that for monoplace chambers, where the average RAS is 414 (95%CI = 234 to 595).

Referral rating:

The referral rating was assigned in 6 referral categories, *A through F*. The average RAS is significantly different between the referral categories (p<0.001), with a trend indicating in-hospital facilities having a lower average RAS than stand-alone facilities.

Figure 5 depicts the relationship between the RAS and the referral category assigned to a facility.

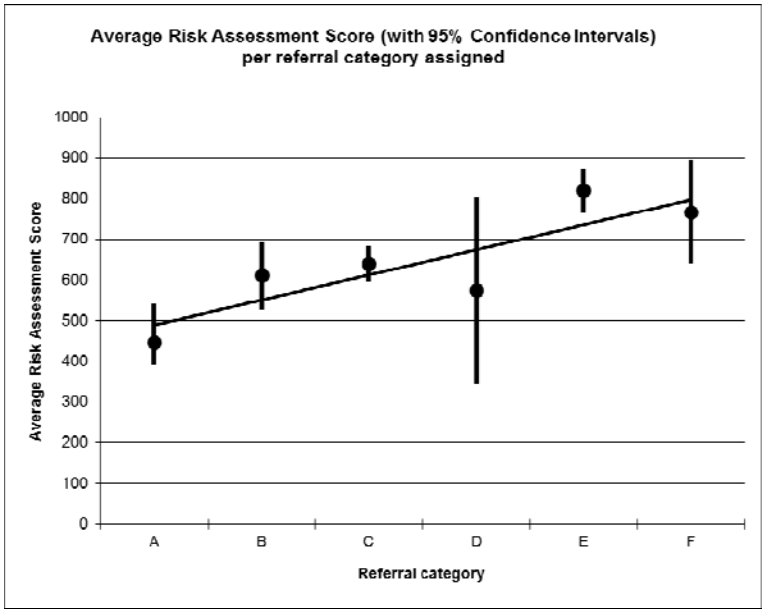

Figure 5: The average RAS by referral category

Availability:

Availability of the facilities to manage recreational diving injuries was categorized as either *open during office hours* (with after-hours support) or *open on a 24/7 basis*. As mentioned in the methods section above, some facilities were not operational (closed) at the time of the assessment and were excluded from this analysis (n=10). The trend indicates increased safety (a lower RAS) with facilities that are more readily available for treatments and this trend is statistically significant ($p<0.001$).

Figure 6 depicts the relationship between the RAS and the availability of the chamber facilities.

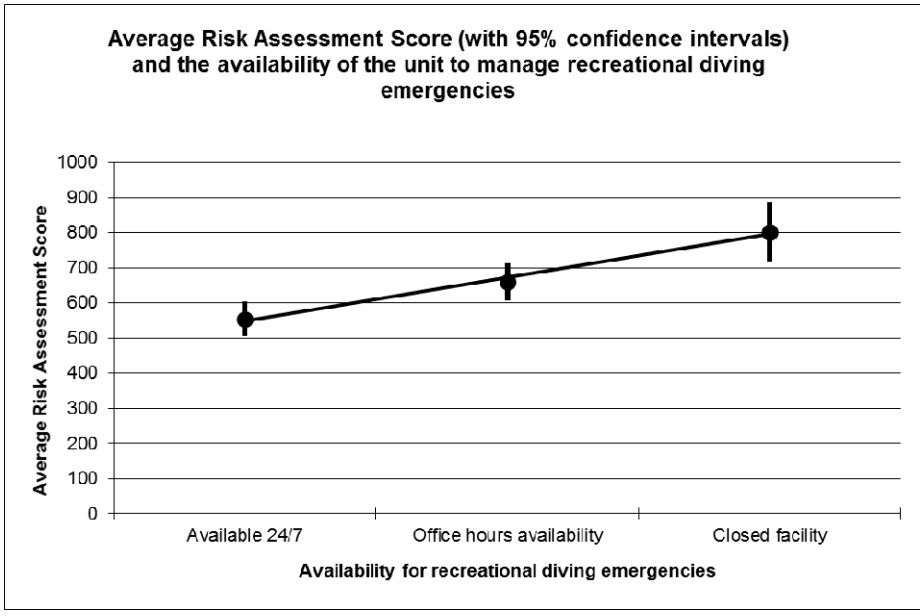

Figure 6: The average RAS in relation to the availability of the facilities

Utilization:

Utilisation of the facility was divided into three categories, namely *low* (less than five patients per year), *normal* (between five and fifty patients per year) and *high* (more than fifty patients per year). Again, a statistically significant trend indicating a lower average RAS with an increase in case load was found ($p<0.001$).

Figure 7 depicts the relationship between the RAS and the case-load of the facilities.

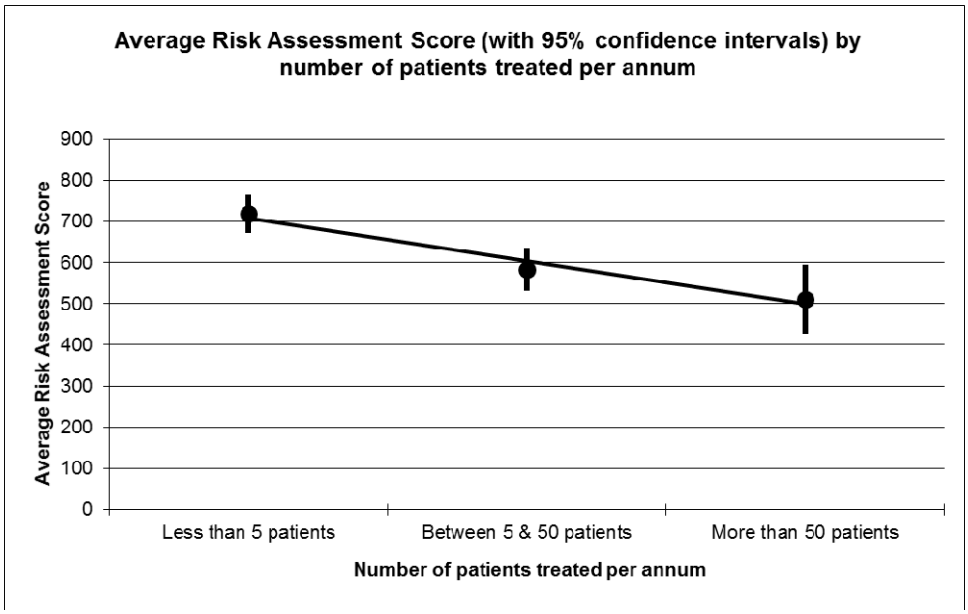

Figure 7: The relationship between the average RAS and the case-load of the facility

Reliability:

The system reliability was rendered either as *reliable* or as *un-reliable*. The RAS was higher for facilities classified as "unreliable" (average RAS = 790; 95%CI = 719 to 861) than those classified as "reliable" (average RAS = 597; 95%CI = 559 to 635), yielding a statistically significant difference ($p<0.001$).

Sustainability:

Sustainability of the facility was dichotomised as *yes* or *no*, based on a combination of factors outlined in the methods section. All facilities were classified as *sustainable* or *unsustainable*. Facilities classified as sustainable had an average RAS of 589 (95%CI = 549 to 629), which was significantly lower ($p<0.001$) than the average RAS of facilities that were classified as unsustainable (average RAS = 766 95%CI = 713 to 820).

Medical supervision:

Medical supervision was indicated as having a *full-time doctor*, an *on-call doctor*, or *no doctor* at all. A lower RAS is associated with increased medical supervision. The 95% confidence intervals overlap, but is probably due to a lack of power, since very few (n=5) facilities had no medical supervision. A non-parametric analysis (Kruskal-Wallis) yielded a p-value of 0.013.

Figure 8 provides a graphical depiction of the relationship between the RAS and the level of medical supervision provided.

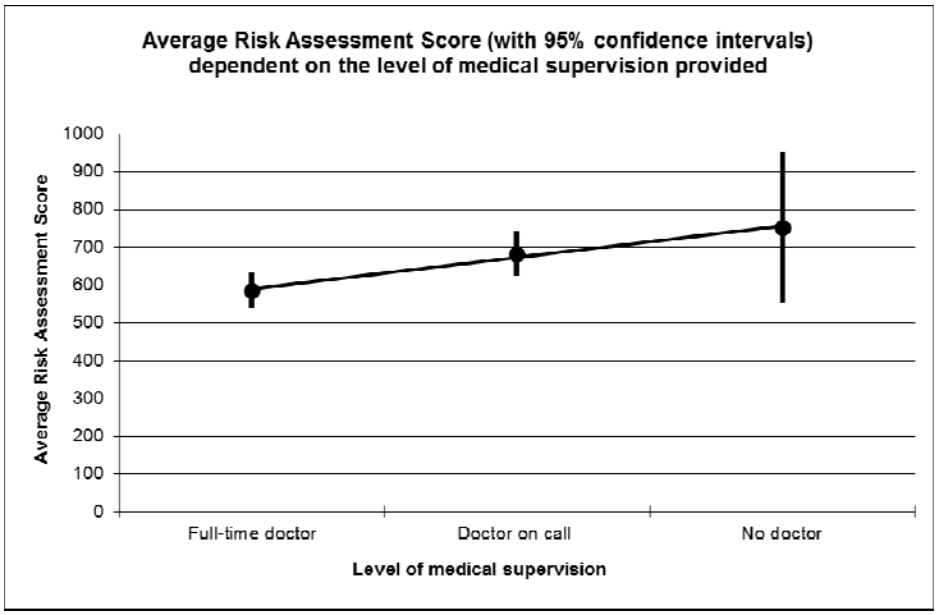

Figure 8: The relationship between the average RAS and medical supervision provided

Staff training:

The staff skillset was categorized by the type of training they had received – *formal*, *informal* or *no training*.

The relationship between the RAS and the training provided to staff members in the facility is depicted in figure 9.

Figure 9: The relationship between the average RAS and staff training

A highly significant trend is present, indicating a lower RAS in staff receiving formal training, compared to informal or no training ($p<0.001$).

The average RAS with formal (i.e., accredited training) training is 404, with the 95%CI = 326 to 482. The average RAS for informal (in-house or on-the-job) training is 676, with the 95%CI = 646 to 706, while the average RAS associated with a lack of training provision is 769 (95%CI = 612 to 925).

Table 5: Summary of study findings (RAS for each associated variable)

Variable (quantity)	Mean (SD)	Median	IQR	95% CI	p-value
Year assessed					
2001 (2)	543 (24)	543	535 - 552	331 - 756	0.083
2002 (9)	678 (93)	680	605 - 748	607 - 749	
2003 (7)	732 (164)	771	735 - 822	580 - 883	
2004 (9)	620 (167)	610	440 - 722	492 - 748	
2005 (12)	686 (90)	702	626 - 734	628 - 743	
2006 (12)	606 (196)	671	442 - 740	482 - 730	
2007 (13)	511 (207)	503	318 - 736	386 - 636	
2008 (18)	704 (166)	755	628 - 824	621 - 787	
2009 (11)	524 (196)	504	429 - 672	393 - 656	
2010 (4)	660 (134)	660	598 - 721	446 - 873	
2011 (6)	589 (257)	596	389 - 816	320 - 859	
Operating age of the facility[1]					
< 1 yr (11)	449 (272)	405	211 - 652	266 - 632	0.117
1-5 yrs (32)	635 (154)	656	552 - 747	579 - 690	
> 5 yrs (54)	620 (168)	680	503 - 743	574 - 665	
Type of treatment protocols (maximum treatment depth) available at the facility[2]					
Up to 300kPa (abs) (15)	494 (248)	503	290 - 739	357 - 631	0.020
Up to 400kPa (abs) (16)	535 (188)	556	420 - 652	435 - 635	
Up to 600kPa (abs) (90)	640 (168)	684	509 - 761	605 - 675	
Type of chamber installed in the facility					
Monoplace (10)	414 (253)	378	207 - 643	234 - 595	0.005
Multiplace (95)	641 (167)	683	513 - 767	607 - 675	
Referral rating or category of the facility					
A[3] (13)	448 (118)	476	435 - 552	390 - 544	<0.001
B[4] (31)	611 (229)	725	445 - 775	527 - 695	
C[5] (48)	640 (150)	680	531 - 738	597 - 684	
D[6] (4)	575 (144)	579	519 - 635	346 - 805	
E[7] (6)	820 (52)	827	799 - 853	766 - 874	
F[8] (3)	767 (51)	757	739 - 789	641 - 893	
Availability of the facility to manage diving injuries					
Available 24/7 (54)	554 (181)	570	443 - 708	505 - 604	<0.001
Office hours (41)	660 (170)	725	610 - 751	607 - 714	
Closed (10)	802 (120)	851	827 - 864	716 - 888	
Utilization of the facility (number of patients per annum)					
< 5 pts (23)	719 (109)	736	669 - 782	672 - 766	<0.001
5-50 pts (50)	585 (183)	618	444 - 745	533 - 637	
> 50 pts (22)	511 (189)	556	411 - 667	427 - 595	
Reliability of the facility					
Reliable (93)	597 (184)	628	486 - 743	559 - 635	<0.001

Variable (quantity)	Mean (SD)	Median	IQR	95% CI	p-value
Unreliable (12)	790 (112)	845	732 - 860	719 - 861	
Sustainability of the facility					
Sustainable (87)	589 (187)	626	471 - 736	549 - 629	<0.001
Unsustainable (18)	766 (108)	782	736 - 857	713 - 820	
Medical supervision: availability of a doctor for the facility					
Full-time doctor (72)	585 (193)	630	463 - 738	540 - 631	0.013
On-call doctor (28)	683 (151)	730	553 - 822	625 - 742	
No doctor (5)	752 (161)	853	688 - 859	553 - 952	
Staff training provided to staff members					
Formal (24)	404 (185)	371	272 - 495	326 - 482	<0.001
Informal (75)	676 (131)	717	586 - 772	646 - 706	
No training (6)	769 (149)	851	728 - 857	612 - 925	

[1] 8 facilities had never operated and were excluded from the analysis in this table

[2] Some facilities have the capability to treat at 400kPa and 600 kPa

[3] A: Hospital-based facilities, with in-chamber advanced life support capabilities.

[4] B: Hospital-based facilities with no in-chamber advanced life support capabilities.

[5] C: Non-hospital based facilities allowing treatments at absolute pressures exceeding 300kPa (abs).

[6] D: Non-hospital based facilities allowing oxygen treatments only.

[7] E: Facilities where a restriction applied due to safety concerns and referral to such facilities were not recommended at the time of assessment.

[8] F: Facilities that were not considered safe at the time of the assessment where no treatments should be provided.

Regression analysis:

The final linear regression model used four factors, namely (1) the type of chamber installed, (2) the number of patients treated per year, (3) the training received by staff members and (4) the availability of the facility to treat diving emergencies[**] to predict the RAS. The model yielded an adjusted R-squared value of 0.541, with the F-test indicating a significance level of <0.001. The final model is described in Table 6.

The ANOVA table for the model is provided as Table 7.

Table 6: Multiple linear regression model to predict the RAS

	Coefficient	Standard Error	t	P > |t|	95% CI
Chamber type (Reference: monoplace)					
Multiplace	144.7	49.7	2.91	0.004	46.1 – 243.2
Both mono- & multiplace	77.3	101.0	0.77	0.446	-123.1 – 277.7
Number of patients treated (Reference > 50 patients/year)					
5-50 patients/year	79.5	32.8	2.42	0.017	14.4 – 144.5
< 5 patients/year	154.8	38.8	3.99	0.000	77.9 – 231.8
(not yet operational)	303.7	71.5	4.35	0.000	161.7 – 445.7
Staff training (Reference: formal)					
Informal training	194.4	32.9	5.91	0.000	129.1 – 259.7
No training	110.9	88.3	1.25	0.213	-64.5 – 286.2
Chamber availability (Reference: available 24/7)					
Available office hours	81.3	27.6	2.95	0.004	26.5 – 136.1
Closed	0	(omitted)			
Constant	209.3	54.4	3.85	0.000	101.3 – 317.3

Table 7: ANOVA table for the regression model

Source	Sum of squares	Degrees of freedom	Mean square	F-value	Prob > F
Model	2111065.75	8	263883.22	16.36	0.0000
Residual	1548871.26	96	16134.08		
Total	3659937.02	104	35191.70		

[**] The sub-group of the predictor "Chamber availability" that was coded as "closed" (for facilities that were closed during the time of the assessment) was omitted from the model because of collinearity.

Chapter 4: Discussion

General

This study provides a unique and valuable insight on leading safety concerns encountered during the assessment of a large portion of hyperbaric facilities used primarily for the treatment of recreational divers around the world. These safety concerns were carefully defined as distinct *risk elements* for the purpose of the analysis.

It is noteworthy that the results contain what could be considered to be *population data* rather than only reporting sample data. This is due to the fact that the global population of hyperbaric facilities eligible for assessment is approximately 160 of which 105 (i.e., 66%) were assessed. The narrow 95%CI range for several RS and RAS and their associated factors illustrates this statistically.

As indicated in Table 3, this review covered a wide, international area and the data had a very high degree of completeness. As all the assessments were made by the investigator using the same Risk Assessment Guide, there was no inter-rater variability to consider.

Risk scores associated with the respective risk elements

One of the primary outcomes of this review was the determination of a suitable risk scores (RS's) for each of the risk elements across the range of facilities assessed. The RS was developed specifically to overcome many of the deficiencies identified in former guidelines. Many of these were effective in recording non-compliances (NC's) but failed to determine their impact on overall safety. The absolute number of NC's does not accurately indicate the overall safety implications of the respective NC's for any given facility. Therefore the various relevant hazards (risk elements), identified as NC's by consistently applying the Risk Assessment Guide, were weighted for their potential impact on safety. Moreover, NC's do not occur in isolation; they also have implications across risk element subdivisions: For instance, the technical section contains certain maintenance and quality-related issues as listed in Table 1. Similarly, certain management items reflected not only on the safety but also the quality of the medical practice evident at the assessed facilities. Accordingly, the categorizations by risk element subdivisions are not definitive of safety or quality and RS values should be used instead.

As described in the methodology, the RS values can be used to allow comparisons and to determine trends based on the associated factors (variables) selected. However, there are also important limitations to using the RS values: The RS is a relative score. Therefore, the data must be interpreted and applied with caution. The RS cannot predict absolute risk nor the incidence rate of a specific accident associated with a NC. However, the RS can rank NC's in terms of their relative importance to safety status across the population of hyperbaric facilities to which it is applied. As such, the RS provides a good indication of a duly weighted and considered risk by incorporating likelihood and severity as well as how often these occur in the field. This provides a relative measure against the other hazards listed and allows the common safety concerns to be identified readily in order of highest RS. Consequently, a higher RS score indicates the presence of a relatively greater number of relevant hazards (risk elements) which can prompt appropriate intervention as well as providing a foundation for ongoing quality assurance. Hence, instead of making arbitrary recommendations, the RS data

provides greater objectivity for the development of targeted safety initiatives and future guidance documents to address such risks.

Table 1 above describes the relevant hazards (risk elements) at the assessed facilities. It provides data on the occurrence (crude number) of each of the relevant hazards over the full spectrum of assessed facilities, the frequency of occurrence (percentage of the full data set), and the weighted risk (RS) associated with each of these elements.

The RS values follow a normal distribution pattern, as shown in Figure 1, with mean of 12 (SD 9, 95%CI = 10 to 14) versus a median of 11(IQR = 14).

Table 2 illustrates the general trend away from technical concerns, towards those involving the human interface and attention.

The descriptive list of relevant hazards provides a comprehensive view of the complexity of a hyperbaric facility. It also indicates that the effective and safe running of a facility requires a multi-disciplinary approach. In addition, a range of skills is required to address and mitigate the various risk elements that exist. However, the scoring system does provide objective guidance on which areas require immediate intervention, and which may possibly be dealt with using other mitigating techniques.

It is of interest to note that the most common safety concerns were made up of 10 risk elements. Not surprisingly, these included management-, technical- and maintenance subdivisions.

There were only 3 purely technical items amongst the top 10. The remaining 7 were all linked to human interactions. This reinforces the point that, for the most part, safety is determined by the medical doctor and the operational team. The exception would be where the technical components are intrinsically unsafe such as may be the case with faulty or sub-standard equipment or installation procedures.

Associated factors

One of the benefits of assigning a risk assessment score (RAS) to each of the hyperbaric facilities is that it permitted other variables (unrelated to NC's or Risk Elements) to be analysed that might be associated with a given RAS. Those associated factors appeared to be predictive are discussed below as well as those where an association was anticipated but not found.

Region:

The assessed facilities covered 105 facilities located in 42 countries in popular recreational diving regions. The results were tabulated per country, with both NC's and RAS values indicated as the mean (median) values per county in order to reflect geographical trends.

The results for the total data set indicated an average number of 37 ±12 NC's at the facilities. The average RAS (taken over all facilities) was 619 ±188 and the median RAS value was 680, with an IQR of 259. These values provide suitable comparators when considering the results from the actual countries.

A review of the association between region and RAS produced counterintuitive findings: The general assertion is that developing countries would be expected to have a greater number of NC's, and thus a higher RAS. However, even a basic review of geography versus the average number of NC's per facility within a given region clearly revealed that this is not necessarily the case. Even when the NC's were weighted to produce the RAS, the pattern remained the same. As such, it would appear that location is not necessarily a good indicator of safety status or awareness. Indeed, there are facilities in developed countries where the NC's and RAS values were well above the mean and median values – Germany (48 NC's and an RAS of 787) being an example. In contrast, there were facilities in developing countries, such as Tanzania (Zanzibar), where the converse was true: 19 NC's listed and an RAS of 309.

A careful review of the raw data revealed two possible confounding factors that could explain the apparent paradox:

- Many popular diving locations lie within developing countries. Treatment facilities are sometimes installed at these sites by diving, medical and resort organisations to specifically assure and attract affluent visitors. Thus an artificial situation may arise where the quality of professional medical and technical support at a given dive site exceeds that in the adjacent parts of the country.

- In some *developed* countries, chambers are established by private clubs catering to injured divers only, whereas in many *developing* countries, these facilities are located in formal healthcare facilities, offering primarily clinical hyperbaric oxygen therapy (HBO) treatments with the treatment of diving illnesses being regarded as secondary.

Although additional subgroup analyses (along the lines of referral ratings followed by determination of the actual location) may refine regional categorizations, these trends were not readily apparent to the investigator. As such it does not appear meaningful or realistic to stratify eligible Hyperbaric Facilities by region in order to predict their safety status.

Year assessed:

Based on the RAS, there did not appear to be any significant difference as the assessment process progressed over time – see Figure 2. This variable was specifically selected as an indicator of process maturity and intra-rater variability: to determine whether there was any degree of either over-reporting or stricter classification of NC's by the investigator during the actual site assessment stages.

There is a wide degree of overlap of the 95% confidence intervals, spanning the entire assessment period. Future investigative analysis using more than just the year of assessment and RAS might indicate other influences.

This subject is also covered under Strength and Weaknesses later in this discussion, but the assessment process does not appear to have been significantly affected by investigator inconsistency.

Operating age:

The data set shows that the greatest number of facilities assessed were those that were well-established, providing a basis for comparison (54 facilities had been in operation for 5 or more years).

The results indicate that the younger the facility, the better the apparent record of safety findings – see Figure 3. The youngest group (n = 11), in operation for less than one year, indicate a RAS_{mean} of 449 compared to the overall value of 619. Facilities in operation longer than 5 years indicate a RAS_{mean} of 621, above the overall average of 619, but lower than the median value of 680. The RAS_{median} for this subset compares well with the overall median value for the data set: 682 vs. 680.

However, these findings should be interpreted with caution, since the findings were not statistically significant ($p = 0.117$). It is thus unclear whether this finding would apply to the population of chambers not yet assessed.

Many of the risk mitigation strategies (and hence the impact of risk weightings) depend on the human interface rather than purely on engineering controls. Most hyperbaric facilities are engineered to a safe standard (in accordance with national and international codes and standards).[22, 26, 27, 59-62] Human factors and ad hoc modifications may still render the system unsafe as a whole, however. As such, an expectation might exist that older facilities would indicate either a greater level of maturity and competence (less non-compliances) or a greater level of negligence or complacency (more non-compliances) with the latter having a greater impact on the RAS than maturity. The progressive escalation in the RAS values over time in operation appears to support this: facilities in operation for less than one year showed the lowest RAS value (mean or median value), whereas the more established facilities had higher RAS values.

Treatment protocols offered (scope of services):

Although the trend line in Figure 4 suggests an increase in the RAS with the progression from shallower, shorter treatment tables towards more complicated deeper protocols being offered, the results were not statistically significant, since the 95% confidence intervals overlap. This is likely due to a lack of power to detect the difference: Although infrequently, most multiplace facilities (n=90) recorded offering treatment tables up to an absolute pressure of 600kPa. This left only a small number of facilities in the shallower treatment groups of which 5 were multiplace and 10 were monoplace-only facilities. Whereas multiplace facilities may elect to limit treatments to 300kPa, monoplace facilities are technically incapable of exceeding 300kPa. As such, a confounding association between chamber type and treatment pressure may have biased the data, justifying an additional subgroup analysis. However, given (1) the small number of purely monoplace chamber facilities (n=10); (2) the fact that they are not favoured for the treatment of injured divers due to their restrictions on treatment pressure as well as the inability to perform sequential neurological assessments during treatment; and (3) the fact that there was a comparable number of multiplace facilities who also did not perform treatments in excess of 300kPa, this analysis proved to be unnecessary. When the data was analysed by means of non-parametric methods (Kruskal-Wallis), a significant difference is found ($p = 0.020$).

The RAS is expected to be higher with more complex treatments on offer. The offering of the basic < 300kPa US Navy Treatment Table 6 (sometimes referred to as the “long oxygen table”) represents the lowest overall risk rating: RAS_{mean} of 515 for this group against the overall mean of 619 (median 680) for all facilities.

One explanation is that higher pressures represent greater exposure to risk. Pressure, operational complexity, training requirements and equipment reliability are all typical areas of concern. This topic is somewhat controversial because some facilities and proponents

claim that deeper treatment depths are more effective in treating residual paralysis.[63, 64] Equally, there are those querying these claims[65] or, after reviewing their own outcomes at deeper pressures, concluding that did not seem to be the case[66].

The 600kPa protocol (specifically the US Navy Treatment Table 6A) was developed specifically for the treatment of arterial gas embolism[67]. However, and specifically related to this study, there are assertions by experienced clinicians that the risk of allowing patients and even staff to enter a saturation condition due to complications in returning from depth renders these treatment protocols unrealistic and possibly even dangerous.[68, 69] These safety considerations clearly weigh heavily against the unproven, anecdotally-proven benefits and there is an increasing trend to discourage the use of 600kPa protocols.

Type of chamber:

Traditionally, diver treatment chambers have been multi-lock (multiplace) chambers, based on standard commercial diving practices.

With the rapid growth of clinical hyperbaric medicine, and the commensurate rise in the placement of less costly, smaller and more resource-manageable single lock (monoplace) chambers, these devices have steadily made inroads into the effective treatment of most types of diving injuries.[70] A typical diver treatment facility is unlikely to be furnished with a monoplace chamber, with some exceptions; however, in some locations, a clinically focussed monoplace facility is called in to treat injured divers. There are actually a few monoplace facilities dedicated to treating divers, but these are less than 5 in number.

A discussion regarding the efficacy or appropriateness of this equipment choice is beyond the scope of this study and in any event, this decision remains the responsibility of the treating medical doctor. However, it is interesting to note that based on this review, a monoplace chamber facility returns a lower RAS at a mean value of 414 (95%CI = 234 to 595), well below the mean of the whole sample studied (RAS_{mean} = 619); while multiplace facilities globally exceed this mean value at a RAS_{mean} of 641 (95%CI = 607 to 675).

There are published advantages and disadvantages to both mono- and multiplace chambers.[70, 71] Yet judging by the RAS outcomes alone, a strong case could be made that a monoplace is a "safer" option to the referring medical doctor, despite the historical preferences for multiplace chambers. However, the selection of a referral facility is not made on the basis of safety. Intervention by personnel is limited in a monoplace facility as is the performance of serial assessments mentioned previously. Indeed, in reality there are also many other contributing factors to consider, especially when considering facilities located in more remote areas. Another example is the addition of life-support equipment. The presence of such equipment may increase the RAS score, yet at the same time, this would be an essential consideration in managing certain clinical situations.

Referral rating:

As a general trend, RAS scores increase the further the hyperbaric facility is located away from a hospital and the closer it is to the dive site – refer to Figure 5.

The first 4 allocations (A, B, C & D: referring to the section Variables, under Study methodology) were not intended to differentiate in terms of safety; these refer solely to the scope of services, location and availability of advance life-support capabilities. The ratings E

and F are generally very carefully decided upon, as the presence, knowledge, training and experience of the presiding medical doctor plays a key role here. It is conceivable that a poor chamber with a good doctor is still a suitable referral centre whereas an excellent chamber without an appropriate practitioner is a greater hazard.

The trend of increasing RAS was statistically significant ($p<0.001$) and the large difference in RAS between the first 4 ratings (A though D) and the last 2 (E & F) concurs with the decision to regard these as "unsafe". The trend allows for a good degree of prediction of the likely safety status, based on the siting of a hyperbaric facility, making it extremely useful as a referral instrument. This referral rating system is now in use by the Divers Alert Network to indicate to the referring doctor whether a facility is suitable or appropriate for referral of an injured diver.

Availability of services:

This indicator delineates between facilities available for diving emergencies (open all hours, all days or 24/7) and those with a more clinical, outpatient market or 8-to-5 focus.

The RAS values are significantly different between all groups, with 24/7 facilities clearly showing the lowest RAS ($p<0.001$). See also Figure 6 for the increasing RAS value as the availability diminishes. The majority of the facilities, 54 of the 105, are open on a 24/7 basis and the results reveal show that such facilities have the lowest RAS_{mean} (554 vs. 619 for all facilities).

The RAS for a 24/7 facility is also influenced by additional safety considerations, such as increased staffing requirements, levels of system redundancy, greater gas supplies and power reserves. To some extent, this implies that a higher RAS should be expected. The result is likely indicative of increased commitment and interest by the facility staff in dealing with diving emergencies; a primary influence in safety awareness and practices.

Utilisation:

A higher utilisation predicts a safer operating environment ($p<0.001$). The increased use of a facility impacts directly on the financial sustainability of the facility, as well as the commitment by staff and familiarisation of staff with equipment – see Figure 3.

An optimal situation is where diver treatments exceed one per week (50+ per year), ensuring that all staff remain familiar with their skills and practices, and that the owners receive sufficient income to provide for proper resources, maintenance and support.

Reliability:

The system reliability, dichotomised as yes or no, was based on the evidenced maintenance regimen. A well-structured and effective maintenance program was considered as sufficient to ensure a reliable facility. The measure was indicated simply as whether or not the facility equipment was deemed to be reliable, notwithstanding other factors, such as sustainability, medical supervision, age or regional location. The direct result was that a high number of reliable facilities emerged (93 out of 105 qualifying results) with an acceptable level of reliability.

A statistically significant difference was found between the RAS of facilities that were deemed reliable and those that were not ($p<0.001$): better maintenance, greater reliability, lower RAS.

However, reliability and safety are not synonymous. Some reliable facilities may have significant safety issues. As such there is the possibility of including less safety-conscious facilities in the overall mix if reliability is used as a predictor of safety. Once again, it is conceivable that an experienced diving medical practitioner can manage with a suboptimal facility, while the converse is not true.

Sustainability:

The determination of this variable was subjective, following the opinion of the investigator and based on knowledge gained of funding (origins), ownership (whether this was stable or changed frequently), income generation and utilisation, prevailing market forces in the region, and also stability and permanence of staff. However, the perception of risk (at the time of the evaluation of the facility) did not play a role in this classification.

It was thus interesting to find that sustainable facilities clearly showed significant differences in RAS values ($p<0.001$) to non-sustainable facilities. This may be explained by the proposition that unsustainable facilities would be less willing or able to address safety concerns.

Medical supervision:

The presence of an appropriately trained doctor was used as the determinant for this variable. The results were plotted as having either a full time, on-call or completely absent doctor on site. Figure 8 indicates the strong relationship between diminishing medical supervision and an increase in RAS values. Due to the small number of facilities (n=5) involved in the category where no doctor is available, the 95% confidence intervals overlap. However, appropriately using non-parametric methods to compare the groups (Kruskal-Wallis), a statistically significant difference is found ($p=0.013$). This is indicative of an increased health and safety risk associated with the absence of a dedicated doctor. This does not reflect on treatment efficacy, but this absence of a doctor would certainly be deemed unsafe in many countries, as well as making for inappropriate referral centres for any organisations engaged in providing remote medical advice.

There is a general understanding that clinical hyperbaric oxygen therapy requires a doctor present whereas commercial diving operations who provide recompression to their employees do not.[59, 72] This leaves facilities treating injured recreational divers a bit in limbo. It is rarely financially rewarding for medical practitioners to be involved in facilities that offer infrequent treatments, thus there is a tendency for these facilities to have on-call coverage by default. Busy facilities almost invariably have a doctor present for the opposite reason.

In some cases, facilities might argue that an on-call only doctor is sufficient, implying that the doctor would assess all patients, but only appear at the facility where deemed necessary either by the actual condition of the patient, or in an emergency declared by the operating staff. This is often the case where codes and standards are misquoted or misunderstood, for example where the doctor is “on call” but has to be present within 3 minutes of being called.[22]

In some extreme cases, specifically where primarily hosted by commercial diving companies, facilities did not believe that a doctor was needed and that a commercial "diver medic" could perform the required recompression therapies.[73] This attitude still prevails amongst certain of the older generation of chamber operators.

Training:

Three categories of training were considered in the evaluation of this variable as an indicator of potential safety. These included formally certified staff, complying with the requirements established by either nationally and internationally recognised staff training systems; staff who had received documented training, but where this was limited to on-site or "on-the-job" training on the specific equipment and provided by in-house staff members; and facilities where staff had received no formal or documented training.

The results indicate a statistically significant trend (see Figure 9) where facilities employing staff trained and certified to recognised standards yielded lower RAS values ($p<0.001$). It is however interesting to find no statistically significant difference between informal (on-the-job) training and having no training available at all. This may again be related to a lack of power to detect a difference.

One would expect that a lack in instruction would render staff less aware of the hazards and the consequences of both actions and omissions, and lead to a less safe working environment. Notably however, both differ significantly from the RAS in facilities where formal training is offered. This is indicative that formal training has a significant effect on the safety of a facility. Training is in fact mandated by most of the relevant national standards[22, 59, 61, 72] and recommended codes of practice or guidelines[8, 25-27] issued by national hyperbaric organisations.

General:

A trend noted in all assessment results, and determined subjectively although corroborated by the data above, is that the safety status, awareness and overall culture is influenced to a greater degree by staff interest, commitment, awareness, training, medical support and leadership. On a global mean, purely technical, infra-structural or even financial issues play a lesser role in rendering a facility safe.

The linear regression model

A significant linear relationship was found between the RAS and the predicting (explanatory) variables. When using this model, the coefficient of multiple determination of the RAS (i.e., the R^2) was 54% using only four variables. The other associated factors described in this thesis were tested for inclusion in the model, but did not yield a better fit. This is likely due to collinearity between the variables. For instance, the "referral category" variable (indicating whether a facility is linked to a hospital or serve as a stand-alone facility) would be adequately predicted by the "facility availability" variable that is included in the model, since in-hospital facilities will typically be available on a 24/7 basis, while more rural facilities would tend to be less available. Another factor playing a role is the small sub-groups contained in some of the variables.

Although the model can be used to predict a RAS of a facility based on these factors, it should be stressed again that such a score should be interpreted with caution, since (in and of

itself) it does not have any predictive value, other than the ability to rank the facility in terms of relative safety compared to facilities already assessed.

Four typical hyperbaric facility examples are used to illustrate the use of this model:

- A new monoplace chamber, which is available on a 24/7 basis, treating more than fifty patients per year, employing formally trained staff, will have a predicted RAS of 209. Table 8 below contains the results of the application of the linear model.

Table 8: Example 1: New hospital-based monoplace chamber facility

	Coefficient	Standard error	t	P > |t|	95% CI
RAS	209.3	54.4	3.85	0.000	101.3 – 317.3

- A new multiplace chamber, available on an out-patient, office-hours basis, treating more than 50 patients per year, employing informally trained staff, will have a predicted RAS of 630. Table 9 below contains the results of the linear model.

Table 9: Example 2: New out-patient based multiplace chamber facility

	Coefficient	Standard error	t	P > |t|	95% CI
RAS	629.7	31.5	19.97	0.000	567.1 – 692.3

- A new multiplace chamber, based outside a hospital on an office-hour basis, treating between 5 – 50 patients per year, employing formally trained staff, will have a predicted RAS of 515. Table 10 below contains the results of the linear model.

Table 10: Example 3: New out-patient based multiplace chamber facility

	Coefficient	Standard error	t	P > |t|	95% CI
RAS	514.7	38.5	13.36	0.000	438.3 – 591.2

- A new multiplace chamber, open office-hours only, treating less than 5 patients per year and with informally trained staff will have a predicted RAS of 785. Table 11 below contains the results of the linear model.

Table 11: Example 4: New office-hour multiplace chamber

	Coefficient	Standard error	t	P > |t|	95% CI
RAS	784.5	30.1	26.02	0.000	724.7 – 844.4

Strengths and weaknesses

This study has the following strengths:

A *significant amount of data* was recorded from the facility assessments, collated consistently (single evaluator) using the Risk Assessment Guide, and containing a high degree of completeness.[5, 8] This meant a low degree of missing data. There was a *wide geographical*

spread, covering the majority of popular diving regions. The c*omprehensive coverage* of all similar facilities world-wide (>66%), implies that a significant portion of the total population was included. Finally, this study is a *first of its kind*, with original data.

However, the study results may be subject to biases and confounding factors that have not been quantified. Four primary sources of potential bias have been identified, namely:

Non-randomness: The assessment program did not include all hyperbaric facilities. It was extensive and estimated to have included around 66% of all recreational diver recompression facilities located close to or within reasonable range of recreational diving sites around the world. Nevertheless this attributes a non-randomness to the data. However, in mitigation of this potential bias, the sites were selected primarily on the basis of strategic value to a region and expressed interest by both the medical director and the diver assistance organisations active within the various geographical regions. The sites were not selected by the investigator and hence bias should not be inferred in this.

Excluded geographic regions: While over 66% of recreational diving treatment facilities have been assessed, regional areas such as Asia Pacific[††] and the Japanese diving region are not included in this analysis. Fortunately, these regions have a low number of facilities included in them. The non-inclusion of these facilities is a result of regional diving-safety political restrictions and is not based on the expected safety status or condition of the facilities. Furthermore, the investigator has visited several facilities in these regions, although not being permitted to formally assess them, and continually fields questions from facilities in these regions. He has observed that as a rule, international standards have been applied to equipment and practices, trends in terms of education, maintenance, safety awareness and equipment condition represent those elsewhere in the world, and that the issues that are raised are the same as those raised elsewhere. While there was no practical way to address this regional bias, no data anomalies are expected to result from this regional exclusion.

Personal bias: The investigator has performed all of the assessments under review as the main assessor. Where assistant assessors were present, their input was limited to data gathering or interaction with staff regarding operating procedures, medical case management or staff training issues. This implies a potential for bias in how the relative importance of non-compliant issues was regarded, and whether in fact these were regarded as a realistic source of risk when considering the entire operating condition of a facility. For example, a facility with a high degree of equipment specification, externally trained and certified staff, effective and consistent maintenance practices and well developed emergency procedures, was less likely to have safety issues with regard to inappropriate or uncertified medical equipment being used inside the chamber. The apparent safety culture evident at a facility played a direct role in whether non-compliances were rated as significant, for recommendation or a comment only. This was a judgment call made by the investigator based on his 18 years' experience in this field. The bias affects rating of non-compliances as well as whether these were even listed.

However, in such cases, the incomplete reporting was likely offset by the greatly reduced probability of significantly negative consequences. This was done using a classical definition

[††] Asia Pacific includes countries such as Australia, New Zealand, the Pacific Rim islands, Indonesia, Philippines, Malaysia, Singapore and Vietnam. The estimate of recreational diver treatment facilities in these regions, based on data obtained from dive safety organisations and recompression chamber networks, is approximately 30.

of "risk" as being the likelihood that the exposure to a hazard will lead to negative consequences.

Process maturity: As the assessments were conducted over an extensive, 13 year period, both the assessor (in this case, the investigator) as well as the process would have undergone various maturations. As such there were increases in efficiency, a reduction in the over-representation of risks in some cases, and a subconscious tendency to focus more quickly on recurrent issues. The effect of this maturity on the data could potentially introduce a degree of inconsistency in the assessment of risks during earlier site assessments, together with the regarding of some risk issues as being less significant as a better understanding of the background and likelihood of negative consequences developed. However, the investigator did have all the appropriate and accurately captured conformance indicators in the body of the reports and thus had access to source data that lies outside of the summarised findings at the end of the reports. Thus at the time of the review, for the purpose of this thesis, all data could be reassessed as raw data with a high level of consistency. In addition, other sources of data (personal notes, photographs, etc.) were also used to verify compliances and non-compliances. It should also be noted that this study was not intended to provide an absolute measure of risks, or a statement of safety at any facility. The impact on the common concerns was hence unlikely to be of significance.

The year of assessment was captured in the raw data set. An analysis of the RAS values indicated no difference in scores over time. This is indicative that even though process maturity may have taken place, the way in which the information was captured for the purposes of this study was consistent.

Sensitivity analysis

Where absolute values are important, or where values are to be compared with data from other assessments, reports or studies, a sensitivity analysis is usually required to determine the effect of any investigator (assessor) inaccuracy or imprecision. Clearly when allocating a risk score in terms of probability and consequence, the investigator would absolutely rely on in-depth personal knowledge of how this would apply to a NC. However, two reasons are submitted as to why a sensitivity analysis was not deemed necessary:

- *De-identification*: The final scoring and the application of the weighting system to the scores was done using the de-identified list and did not rely on knowledge of the individual facilities, but rather only the understanding of how the relevant hazard (risk element) could be scored in terms of probability and consequence. Hence no bias or altered rating to any facility could be implied. The outcome would thus treat all facilities equally.

- *Accuracy*: The actual accuracy of final risk assessment scores is not critically important. The primary goal in obtaining a score is simply to prioritise NC's and hence to extract the most common NC's that have a direct impact on facility safety, as well as prioritising individual RAS's in order to rank facilities relative to each other.

Chapter 5: Conclusions

Hyperbaric facilities exist in a range of forms, from formally-established, hospital-based units in well-developed regions through to basic ex-commercial diving chambers in remote, popular diving spots.

This review of 105 such facilities, over an extensive, 13 year period, was able to determine the most common safety concerns together with the associated factors that have an influence on the overall safety status of these treatment facilities. By applying the Risk Assessment Guide to produce risk scores related to non-compliances, risk assessment scores could be derived for each hyperbaric facility.

Importantly, these scores made provision for a linear regression analysis to identify associated factors upon which a predictive model could be based. The latter now allows for the likely risk profile of any hyperbaric facility relative to the other facilities within the global population, while using only four of the associated variables.

The outcome of the determination of individual risk scores was the ranking of these to determine those that play the most significant role in establishing the overall risk assessment score of hyperbaric facilities. This study produced a means to empower referring medical practitioners to be able to make more informed decisions on the likely safety status of a hyperbaric facility, even where such a facility is truly remote and in an inaccessible part of the world. By doing so, it may be anticipated that injured divers may receive better care with fewer complications.

This work has established an important foundation upon which further research may be built. It has unmasked and ranked the salient risk elements in a way that they may be studied further. It also provides safety directors and medical directors with a prioritised outline for ongoing quality assurance and safety improvement.

Two offerings are rendered in final conclusion.

- *Human interaction is the most important variable in determining safety*: This study projects the clear message that despite the usual assumption that safety is dependent on the technical or engineered aspects of any facility, the most essential contributors to safety are all the human interactions including management, administration and operation of the facility. This conclusion is based on the findings in this report as well as reviews of accidents.[7] Safety lies directly within the control and capability of those that manage and operate the facility: once a facility has been properly established it rarely needs a highly technical mind to provide safety assurance.

- *Failure to plan produces planned failure*: The second, related in the sense that it is the creed of the engineer, but also the adage taught to all SA Navy candidate officers during training in 1984 and echoed in numerous medico-legal reviews, states that those that fail to plan, plan to fail! What better illustrates this point than having the highest risk score attributed to the failure to practice safety drills – it is too late to realise during a real emergency that the plan was doomed to failure!

Chapter 6: Recommendations

Two areas of consideration for additional studies, research and analysis include the refinement of the scoring system and the associated variables.

Further areas for analytical studies:

Neither the risk scores nor the risk assessment scores are absolute values. This remains the ultimate objective, however – the determination of absolute risk. Nevertheless, in this study, risk scores and risk assessment scores were used to rank safety concerns and hence to develop guidance for prediction and where due attention should be paid to improve safety. Taking this further towards quantitative analysis techniques to derive absolute values for risk might allow accurate prediction of incidence rates for specific accidents related to identified safety concerns. Unlike the aviation industry, hyperbaric medicine is not driven by the same economic impetus nor the same level of public insistence on near-absolute safety. As such, it may prove to be impractical to derive absolute risk given the paucity of chambers and the relative scarcity of accidents.

Several of the associated variables were not deemed significant enough due to size of sub-groups, or were excluded due to potential collinearity between the variables. This does not mean to suggest the absence of any other factors. Therefore, these variables could be explored and refined further in order to improve the adjusted R-squared value as well as to refine the basis of referrals or deferrals in favour of evacuation to another facility.

Lastly, other significant associated factors may become apparent during future assessments, such that the R-squared value may be raised above the present 54% mark.

Development of guidance based on risk scores:

The study has enabled the actual hyperbaric facility risks or safety concerns to be examined and ranked. This has provided a range of items that can be researched and studied further with the objective of providing medical directors or even users or facility owners with practical ways to mitigate and suitably address these concerns.

The following five safety concerns, listed in decreasing order (i.e., by magnitude of risk score in the range 33 to 0), represent key areas that can be studied further to render appropriate advice to hyperbaric facilities.

- *Regular emergency drills not carried out.* This was rated the most common safety concern and was observed at 85% of the assessed facilities, with a safety indicator or RS of 33. Research into the rationale behind the importance of conducting regular drills, together with practical guidance on better management of this area of concern, would provide those responsible with enhanced confidence in the operation of their facilities.

- *No alternative breathing gas device provided for the chamber operator*. This carried a risk score of 32 and occurred at 87% of the assessed facilities. The intent of this requirement is to ensure that in the case of a fire in the facility (but outside the chamber) the operator would be able to complete the decompression of the occupants

to get them to safety. Clear, established international requirements exist.[59, 61] Nevertheless, this finding rated as the second most common technical safety concern at the facilities assessed. In order to address this effectively, users would need to understand the reasoning behind the selection and implementation of suitable emergency equipment.

- *Emergency operating & medical procedures not documented.* Ranked third, with a risk score of 31, this area of non-compliance was common to 78% of the facilities assessed. While medical and operational requirements are generally well described and documented in most areas of medicine, legal requirements and ramifications are not always obvious or well understood. This topic requires further research and delineation for the responsible medical doctor.

- *Leak testing not done.* This returned a risk score of 28 and occurred at 74% of the assessed facilities. The appropriate way to facilitate compliance with this safety requirement would be to provide researched guidance on the risk *rationale* together with practical, field-appropriate execution methods.

- *Maintenance system absent, inadequate or inappropriate.* This was the fifth highest safety concern with a risk score of 28; it was observed at 66% of the assessed facilities. Further research into the likely causes for this, with suitable managerial and safety-related guidance for effective implementation, would provide suitable remedies to address this concern.

APPENDIX A

RISK RATINGS

Probability/likelihood of an event/accident happening					
Fire risk		**Mechanical risk**		**Health risk**	
Combustion definite	5	Failure definite	5	Event definite	5
Combustion expected	4	Failure expected	4	Event expected	4
Combustion possible (in theory)	3	Failure possible	3	Event possible	3
Combustion unusual	2	Failure unusual	2	Event unusual	2
Combustion unlikely	1	Failure unlikely	1	Event unlikely	1

Severity/consequence of an incident/exposure/event	
Catastrophic (e.g. every chance of death, serious injury or destruction)	5
Severe (e.g. facility no longer available for treatment or significant injury)	4
Serious (e.g. reduced ability to treat, affecting treatment quality)	3
Significant (i.e. minor damage or injury, or extra staff engagement)	2
Noticeable (i.e. inconvenience & additional work required)	1

APPENDIX B

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